

105th Congress }
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SENATE

{ REPORT
{ 105-32

**PRODUCT LIABILITY REFORM ACT OF
1997**

R E P O R T

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND
TRANSPORTATION

ON

S. 648

together with
MINORITY VIEWS



JUNE 19, 1997.—Ordered to be printed

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ONE HUNDRED FIFTH CONGRESS

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105TH CONGRESS }
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PRODUCT LIABILITY REFORM ACT OF 1997

JUNE 19, 1997.—Ordered to be printed

Mr. MCCAIN, from the Committee on Commerce, Science, and
Transportation, submitted the following

REPORT

together with

MINORITY VIEWS

[To accompany S. 648]

The Committee on Commerce, Science, and Transportation, to which was referred the bill (S. 648) “A Bill to establish legal standards and procedures for product liability litigation, and for other purposes”, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

PURPOSE OF BILL

The bill, S. 648, creates certain standards of product liability law that are to be applied uniformly throughout the United States.

The present system in the United States for resolving product liability disputes and compensating those injured by defective products is costly, slow, inequitable, and unpredictable. Such a system does not benefit manufacturers, product sellers, or injured persons. The system’s high transaction costs exceed compensation paid to victims. Those transaction costs are passed on to consumers through higher product prices. The system’s unpredictability and inefficiency have stifled innovation, kept beneficial products off the market, and have handicapped American firms as they compete in the global economy.

S. 648 addresses these problems through several changes to existing product liability law. This new law would apply to all product liability actions in state and federal courts. These changes are balanced and limited and are intended to reduce transaction costs, provide greater certainty as to the rights and responsibilities of all

parties involved in product liability disputes, encourage innovation, increase the competitiveness of U.S. firms, reduce burdens on interstate commerce, and safeguard due process rights.

In Title II, the bill seeks to avoid a public health crisis by specifically addressing an emerging problem concerning the supply of medical devices. The supply of raw materials and component parts used in medical devices—commonly referred to as biomaterials—is jeopardized because suppliers of those biomaterials are pulled into product liability suits primarily targeted at the manufacturer of the medical device. Although courts are not finding suppliers of biomaterials liable, the costs of defending these suits are far greater than the profits from supplying the biomaterials for use in medical devices. Suppliers of biomaterials are, therefore, refusing to supply raw materials and component parts to the manufacturers of medical devices. As a result the supply of life-saving and life-enhancing medical devices is jeopardized. To address this important public health problem, S. 648 would allow the suppliers of raw materials and component parts used in medical implants to obtain dismissal from certain tort actions without extensive discovery or other legal costs. The provision would not affect the ability of claimants to sue manufacturers or sellers of medical implants and it would not apply to lawsuits involving silicone gel breast implants.

BACKGROUND AND NEED

INTRODUCTION

Although product liability is a matter traditionally left to state law, the current morass of product liability laws is a problem of national concern that requires Congressional action. The current system of compensating people injured by defective products is costly, slow, inequitable, and unpredictable.

Many consumers who are injured by defective products and deserving of compensation are unable to recover damages or must wait years for recovery. They, like manufacturers and product sellers, are thrust into a product liability litigation system in which identical cases can produce startlingly different results. Moreover, severely injured victims tend to receive far less than their actual economic losses, while those with minor injuries often are overcompensated.

Inefficiency and unpredictability have many negative effects. The unpredictable patchwork of state laws has had a chilling effect on the introduction of new products to market. The current U.S. product liability system also damages our competitive position in world markets because the excessive costs of the system result in higher prices for American products.

The present system adversely affects manufacturers, product sellers, consumers, and individuals injured by products. Reform by the states cannot fully address the problems with the current product liability system. Reform at the federal level is urgently needed.

I. PROBLEMS WITH THE PRESENT PRODUCT LIABILITY SYSTEM

The existing system does not provide an efficient and equitable means of resolving claims involving defective products.

A. COSTS ARE HIGH AND CONTINUE TO ESCALATE

The costs of the product liability system have increased substantially in recent decades. The editors of *The Liability Maze*, a book published by the Brookings Institution in 1991, noted that “[r]egardless of the trends in tort verdicts, most studies in this area have concluded that, after adjusting for inflation and population, liability costs have risen dramatically in the last thirty years, and most especially in the last decade.”¹ Increases in awards in such cases have been much higher than corresponding increases in wages and inflation.² Increased product liability costs are reflected in dramatic increases in liability insurance costs. Over the last forty years, general liability insurance costs have increased at over four times the rate of growth of the national economy.³

The transaction costs associated with the present product liability system—the costs of litigation, court proceedings, and attorneys’ fees—are enormous. Today, plaintiff and defense lawyers collect as much from the system as injured persons do and most of the money paid out by manufacturers never reaches injured persons.⁴ A study by the Insurance Services Office (ISO) of closed claims in 1992 indicated that for every \$10 paid to claimants by insurance companies in product liability cases, another \$7 is paid for lawyers and other defense costs.⁵ If the contingent fees of plaintiffs’ attorneys are factored in, lawyers’ fees account for 61 percent of the funds expended on product liability claims.

A 1986 study by the Rand Institute for Civil Justice showed that the annual overall transaction costs of the U.S. tort system exceed compensation to plaintiffs. The Rand study found that in 1985, net compensation totaled \$13 billion to \$15 billion, but the transaction costs—including plaintiffs’ attorneys’ fees, defense legal fees, public expenditures, and the time of the litigants—were between \$15 billion and \$19 billion.⁶ A study conducted by the insurance industry in 1989—the Tillinghast study—estimated the current overall annual cost of the U.S. tort system at a staggering \$117 billion.⁷

¹Peter W. Huber and Robert E. Litan, eds., *The Brookings Institution, The Liability Maze* 3 (1991). [Hereinafter *The Liability Maze*].

²P. Weiler, K. Abraham, R. Rabin, D. Rosenberg, A. Schwartz, W.K. Viscusi, *Enterprise Responsibility for Personal Injury*, American Law Institute, Reporters’ Study, Vol. I, at 270-71 [hereinafter ALI Reporters’ Study].

³Id. at 60.

⁴Testimony of the Honorable Robert A. Mosbacher, Secretary, U.S. Department of Commerce, Before the Consumer Subcommittee of the Senate Committee on Commerce, Science, and Transportation, S. Hrg. 101-743 at 258, April 5, 1990 (hereinafter April 5, 1990 hearing).

⁵Insurance Services Office Product Liability Closed Claim Survey, A Technical Analysis of Survey Results (1992).

⁶Testimony of James S. Kakalik, Ph.D., The Institute for Civil Justice of the Rand Corporation, before the Subcommittee on Trade, Productivity, and Economic Growth of the Joint Economic Committee, July 29, 1986, S. Hrg. 99-1090. The same conclusion was reached in a study done by an actuarial consulting firm for members of the insurance industry. The study found that in 1984, 63 percent of the gross insured costs of the United States tort system consisted of payments to claimants. Robert W. Sturgis, “The Cost of the U.S. Tort System,” Tillinghast, Nelson, and Warren, Inc. 16 (November 1985). If this is reduced by one-third to account for plaintiffs’ attorneys’ fees, only 42 percent of the costs remain to compensate the injured. Dr. Kakalik, author of the Rand study, explained in his testimony that Sturgis’ estimate of transaction costs “is higher than ours because it includes the cost of insurance premiums that cover claims, lawsuits, and the operation of the insurance system. We only report on compensation and costs directly associated with tort lawsuits.”

⁷Tillinghast, Perrins-Tower Group. *Tort Cost Trends: An International Perspective* 16 (December 1989).

The U.S. tort system is by far the world's most costly tort system.⁸ Consumers pay higher prices as a result. Neither plaintiffs nor defendants benefit from the rapidly increasing and excessive costs of the present system for resolving product liability disputes.

B. DELAY

Product liability suits take a very long time to process. This delay places at a disadvantage those injured by faulty products and adds to the expense of the civil justice system.

One insurance industry study found those with the most severe injuries are forced to wait the longest for compensation. This study found that, in cases where payment exceeded \$100,000, 21.6 percent of claimants waited more than five years for payment. Only 2.1 percent were paid within a year of reporting their injury, and 62.6 percent took more than three years to be paid.⁹

A GAO report found that, in the five states studied, on average product liability cases took two and one-half years to move from filing to trial court verdict.¹⁰ One case studied by GAO took about nine and one-half years to move through the court system.¹¹

Most product liability cases are settled before trial, but even these cases suffer from delay. One plaintiff's attorney explained that "most settlement negotiations get serious only a week or so before trial is scheduled to begin." This timing has become so ingrained in the system that "each week the [lawyer's] firm projects cash flow by estimating the settlement value of the cases set for trial the following week."¹²

Delay can result in undercompensation of victims. Many injury victims are forced to settle their claims for less than their full losses so they can obtain compensation more quickly. These individuals are often forced into this decision because they have inadequate resources to pay for their medical and rehabilitation expenses. This dynamic is most evident where severe injuries are involved.¹³

C. INEQUITABLE COMPENSATION

The present product liability system also is unfair because it fails to compensate those injured in proportion to their losses. Numerous studies have found the tort system grossly overpays people with small losses, while underpaying people with the most serious losses.

An early ISO product liability study found injured plaintiffs with losses between \$1 and \$1,000 receive, on the average, 859 percent of their losses, while those with losses of over \$1 million receive, on the average, 15 percent of their losses (before paying their attor-

⁸ Id.

⁹ Alliance of American Insurers Survey of Large-Loss Product Liability Claims 4 (1980).

¹⁰ U.S. General Accounting Office, Report to the chairman, Subcommittee on Commerce, House Committee on Energy and Commerce, "Product Liability: Verdicts and Case Resolution in Five States" 49 (September 1989) [hereinafter GAO Report].

¹¹ Id.

¹² Wayne E. Green, A Lawyer Faces Risks In Deciding to Take On Costly Damage Suits, Wall St. J., May 23, 1986 at 12.

¹³ See Jeffrey O'Connell, A 'Neo No-Fault' Contract in Lieu of Tort: Preaccident Guarantees of Postaccident Settlement Offers, 73 Calif. L. Rev. 898, 901-902 (1985).

neys' fees).¹⁴ In general, the study found compensation exceeded economic loss when losses were below \$100,000, but compensation dropped dramatically below actual economic loss when the claimant's loss exceeded \$100,000.¹⁵

D. UNPREDICTABILITY

Consumers, manufacturers, and product sellers are trapped in a product liability litigation system that has been called a lottery. Identical cases can produce startlingly different results.

A principle cause of excessive uncertainty is the diversity in legal standards applied in different jurisdictions.¹⁶ Professor M. Stuart Madden of Pace University School of Law, in his testimony before the Subcommittee on April 4, 1995 identified the "cacophony of conflicting state liability and damage rules" as the primary cause of this confounding unpredictability.¹⁷ Professor Madden explained:

While analyzing the array of diverse state laws is festive for academics, it is costly to businesses and to the public. Studies show that insurance costs in the United States are twenty times greater than they are in Europe, and fifteen times greater than in Japan.¹⁸

Art Kroetch, Chairman of Scotchman Industries, a small business that manufactures machine tools in South Dakota, indicated in his testimony before the Subcommittee on April 4, 1995 that the uncertainty concerning both the applicable product liability rules and the resultant exposure business faces is reflected in erratic product liability insurance rates. Mr. Kroetch explained that insurers "are unable to accurately predict potential liability due to the disparity in state laws, unpredictability of where the product will be located initially, and later where it is sold and resold as used equipment." Mr. Kroetch indicated that when insurance companies set their rates, they must account for the worst case scenario and, as a result, insurance rates are sometimes so high that affordable coverage cannot be obtained.¹⁹

The system's unpredictability particularly affects settlements as negotiations are "sabotaged" by the lack of clear standards.²⁰ For example, uncertainty over the liability standards for punitive damages makes it difficult to negotiate sensibly where punitive damages are alleged.²¹

Greater predictability and uniformity will benefit all parties in product liability disputes. Warren W. Eginton, a federal judge and

¹⁴ Insurance Services Office Product Liability Closed Claim Survey, A Technical Analysis of Survey Results (1977) at 49.

¹⁵ *Id.* at 383.

¹⁶ See, e.g., S. Rept. 98-476, pp.3-4; Calabresi and Klevorick, Four Tests for Liability in Torts, 14 J. Leg. Stud. 585, 585-6 (1985).

¹⁷ Testimony of Professor M. Stuart Madden, hearing of the Subcommittee on Consumer Affairs, Foreign Commerce and Tourism, Senate Committee on Commerce, Science, and Transportation, April 4, 1995 (hereinafter April 4, 1995 hearing), S.Hrg. 104-335 at 364.

¹⁸ *Id.* at 364.

¹⁹ Testimony of Art Kroetch, April 4, 1995 hearing, S.Hrg. 104-435 at 351.

²⁰ Twerski, A Moderate and Restrained Product Liability Bill: Targeting the Crisis Areas for Resolution, 18 U. Mich. J. of L. Ref. 575, 612 (1985).

²¹ Testimony of Professor Aaron Twerski, Hearing of the Consumer Subcommittee of the Senate Committee on Commerce, Science, and Transportation, September 19, 1991 (hereafter September 19, 1991 hearing), S. Hrg. 102-727 at 104 (1991). See Twerski, A Moderate and Restrained Federal Product Liability Bill: Targeting the Crisis Areas for Resolution, *supra*, at 612.

a product liability expert, testified at the Subcommittee's hearing on February 22, 1990 that:

the more uniformity can be accomplished . . . the more quickly the litigation will flow and the lighter the economic burden on all parties involved. Certainly the task of the judge and juries in understanding the problems and the rules of law to be applied to those problems will be greatly simplified by uniformity.²²

The uncertainty in the present system is a serious problem for both plaintiffs and defendants. Plaintiffs need faster, more certain recovery that fully compensates them for their real losses. Defendants need greater certainty as to the scope of their liability.

II. BURDENS FROM A PRODUCT LIABILITY SYSTEM THAT HAS FAILED

Our nation's inefficient and inequitable product liability system burdens consumers with higher prices and deprives them of needed products. It ladens businesses with unnecessary costs that injure their international competitiveness and sacrifices quality American jobs. An inefficient and inequitable product liability system does not foster safety.

A. CONSUMERS PAY HIGHER PRICES AND ARE CONFUSED ABOUT THEIR RIGHTS

William Fry, Executive Director of HALT, indicated in his testimony before the Subcommittee on April 3, 1995 that ordinary consumers would benefit from product liability reform. HALT is a "nonprofit organization of 70,000 individuals devoted to reforming the legal system so that it works better for the average citizen."²³

Mr. Fry indicated the diversity of product liability laws applied by different states frustrates consumers because "they cannot know their basic rights and options, and . . . they must consult a lawyer to find them out."²⁴ HALT supports a federal product liability law to give consumers consistency and predictability, and to enable them to learn and understand their rights.

Consumers must ultimately bear, through higher prices, the excessive costs of our product liability system. Mr. Fry testified, for example, that excessive punitive damages "penalties are harmful to business and to consumers of products when price reflects the risk of such penalties."²⁵ He also noted that "our members are sensitive to the pass-through impact of punitive damages, or the fear of them, to consumers in the form of higher prices or products not getting to market."²⁶

²²Testimony of the Honorable Warren W. Eginton, U.S. District Judge, District of Connecticut, S. Hrg. 101-743 at 180 (1990).

²³Testimony of William Fry, hearing of the Subcommittee on Consumer Affairs, Foreign Commerce and Tourism, Senate Committee on Commerce, Science and Transportation, April 3, 1995 (hereinafter April 3, 1995 hearing), S.Hrg. 104-435 at 83.

²⁴Id. at 85.

²⁵Id. at 88.

²⁶Id. at 89.

B. WOMEN'S HEALTH RESEARCH AND PRODUCTS: A CASE STUDY OF A
BROKEN SYSTEM

In its many hearings over the years, the Committee has often received testimony about how the existing product liability system stifles innovation and keeps beneficial products off the market. A compelling example is the testimony received by the Subcommittee on April 4, 1995 from Ms. Phyllis Greenberger, the Executive Director of the Society for the Advancement of Women's Health Research. The Society is a "non-profit, non-partisan organization committed to improving the health of women through research."²⁷

Ms. Greenberger testified that the Society believes "the current liability climate is preventing women from receiving the full benefits that science and medicine can provide." She noted "there is evidence that maintaining the current liability system harms the advancement of women's health research." This harm occurs because "[l]iability concerns are stifling research and development of products for women."

Ms. Greenberger stated that "[c]ontraceptive development in the U.S. provides an excellent example of how the threat of litigation can devastate an entire industry." She noted it is litigation concerns, not a lack of demand, that has reduced the number of U.S. companies doing contraceptive research from 13 to 2. Ms. Greenberger stated that a "recent report of the Institute of Medicine attributed this decline to the unpredictable nature of litigation combined with the enormous cost and limited availability of liability insurance."

It is not just research that is affected. "Liability concerns are keeping products, which have already been developed, off the market despite a known therapeutic need." Ms. Greenberger gave several examples of beneficial products which are not being marketed, including Bendectin, the only anti-nausea medication ever approved by the Food and Drug Administration for use during pregnancy.

To understand these unfortunate developments, Ms. Greenberger advised that if one "[v]iews the legal landscape from the eyes of a manufacturer, one sees a foreboding terrain." She notes that "[i]t is important to remember that the very nature of drugs and medical devices means that they are not risk free." Consequently, "[a]ny drug taken over long periods of time by large populations will undoubtedly result in problems for a certain number of people." Ms. Greenberger stressed that "unintended adverse reactions in a few should not create a threat of liability so great as to disadvantage the many who benefit."

Ms. Greenberger identified the true risk to such beneficial products when she noted they "present an enticing arena for lawyers who have created an industry out of cultivating massive, sensationalized lawsuits often based on the experience of the few who experienced legitimate problems." In addition, Ms. Greenberger commented that her organization "is concerned that opponents to re-

²⁷Testimony of Phyllis Greenberger, April 4, 1995 hearing, S.Hrg. 104-435 at 210.

form are using women as their strategy to block change” in product liability.²⁸

C. INNOVATION IS STIFLED AND BENEFICIAL PRODUCTS ARE KEPT OFF THE MARKET

The negative effect of our current product liability system on the economy was clearly demonstrated in a survey of over 2,000 CEOs conducted by the Conference Board in 1988. Participating businesses indicated their actions were affected in the following ways by our current product liability system.

ADVERSE IMPACTS CITED BASED ON ACTUAL LIABILITY EXPERIENCE²⁹

Type of Impact Reporting Action:	Percent of Firms:
Closed Production Plants	8
Laid Off Workers	15
Discontinued Product Lines	36
Decided Against Introducing New Products	30
Decided Against Acquiring/Merging	17
Discontinued Product Research	21
Moved Production Offshore	4
Lost Market Share	22

ADVERSE IMPACTS CITED BASED ON ANTICIPATED LIABILITY PROBLEMS³⁰

Type of Impact Reporting Action:	Percent of Firms:
Closed Production Plants	1
Laid Off Workers	1
Discontinued Product Lines	11
Decided Against Introducing New Products	9
Decided Against Acquiring/Merging	5
Discontinued Product Research	4
Move Production Offshore	1
Lost Market Share	

In his testimony before the Subcommittee in 1990, Secretary of Commerce Robert Mosbacher testified that the Conference Board results show the extent of the indirect costs of the current product liability system. These indirect costs include “useful products . . . being discontinued, decisions not to develop new product lines or not to continue product research, and a fear to innovate.”³¹ Many

²⁸ All quotations in the preceding paragraphs are from Greenberger’s testimony, April 4, 1995 hearing, S.Hrg. 104–435 at 211–212.

²⁹ McQuire, The Conference Board, Research Report No. 908, 19 The Impact of Product Liability Table 28 (1988) [hereinafter Conference Board Report].

³⁰ Conference Board Report Table 29 at 19.

³¹ Testimony of the Honorable Robert A. Mosbacher, April 5, 1990 hearing, S. Hrg. 101–743 at 247 (1990).

U.S. companies devote far more to product liability costs than to research and development efforts. For example, The National Machine Tool Builders Association (now called the Association for Manufacturing Technology) stated its members spend seven times more on product liability costs than on research and development.³²

Product development is hindered in many ways by our existing product liability system. Sometimes, due to fears about joint liability, raw material suppliers refuse to sell necessary materials to manufacturers for new product concepts.

For example, Ms. Julie Nimmons, Chief Executive Officer of Schutt Sports Group testified in 1993 that material suppliers are reluctant to sell to her company, a manufacturer of protective sporting goods equipment, for fear of liability. This reluctance sometimes kills new product development. Ms. Nimmons' company designed a new baseball product that functioned well in prototype testing, but the company was unable to produce the product because it could not obtain needed materials.³³ More recently, the company chose not to produce hockey helmets, even though interest in the sport has grown substantially in the United States. "In the final analysis," she said, "we felt we could not pursue this market because of the additional, uncontrollable liability exposure it would create."³⁴

This "chilling effect" extends beyond product manufacturers. In his testimony before the Subcommittee in 1990, Secretary Mosbacher referenced reports that:

Universities are shying away from licensing patents to small manufacturers because of their fear that, as the originators of the idea upon which a product was manufactured, they will become the 'deep pocket' if there is litigation involving the product.³⁵

This development is distressing because it is widely accepted that small companies play a crucial role in innovation.

A report by the American Medical Association indicates the current product liability system also is having a "profoundly negative impact on the development of new medical technologies."³⁶ The report concluded:

Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safe-

³²Testimony of Howard H. Fark, February 22, 1990 hearing, S. Hrg. 101-743 at 225-26.

³³Testimony of Ms. Julie Nimmons, hearing of the Consumer Subcommittee, Senate Committee on Commerce, Science and Transportation, September 23, 1993, S. Hrg. 103-490 at 20.

³⁴Testimony of Ms. Julie Nimmons, hearing of the Senate Committee on Commerce, Science and Transportation, March 4, 1997, at 2.

³⁵Testimony of the Honorable Robert A. Mosbacher, April 5, 1990 hearing, S. Hrg. 101-743 at 249 (1990).

³⁶Testimony of Richard Kingham, April 5, 1990 hearing, citing, AMA Board of Trustees, "Impact of Product Liability on the Development of New Medical Technologies," at 12 (June 1988) in Brief of Amici Curiae Pharmaceutical Manufacturer Association and American Medical Association in *Browning Ferris Industries of Vermont, Inc. v. Kelco Disposal, Inc.*, 109 S. Ct. 2909 (1989).

ty or efficacy, but because product liability suits have exposed manufacturers to unacceptable financial risks.³⁷

Not only is actual product development suppressed, even basic scientific research is squelched by our product liability system. Dr. Malcolm Skolnick testified before the Subcommittee during the 101st Congress that:

Scientific inquiry is stifled. Ideas in areas where litigation has occurred will not receive support for exploration and development. Producers fearful of possible suit will discourage additional investigation which can be used against them in future claims.³⁸

In 1992, *Science* magazine reported that liability concerns led at least two companies to delay AIDS vaccine research and another company to abandon a promising approach.³⁹

Even established, beneficial products sometimes fall prey to our broken product liability system. For example, in 1984 two of the three companies manufacturing the diphtheria-tetanus-pertussis (DTP) vaccine decided to stop producing it due to product liability costs. Later that year, the Centers for Disease Control recommended doctors stop vaccinating children over age one in order to conserve limited supplies of the DTP vaccine for the most vulnerable infants.⁴⁰

D. U.S. COMPETITIVENESS IS HAMPERED

American business faces a competitive disadvantage in both international and domestic markets due to our flawed product liability system. American manufacturers and product sellers generally pay product liability insurance rates that are 20 to 50 times higher than those of foreign competitors.⁴¹ This disparity is attributable, in large part, to the uncertainties and costs of the American tort litigation system.⁴² Insurers generally do not discount premiums when a manufacturer exports its goods, because there is a possibility that a product-related suit will be brought in the United States. Consequently, each U.S. product shipped abroad contains an insurance cost element greater than that of a foreign competitor.⁴³ In the ever more competitive international markets, the resultant price differences hamper American business.

American business is similarly disadvantaged in our domestic market when foreign companies enjoy a lower cost base due to their less expensive and more certain product liability systems. Often, the over-all cost base of foreign manufacturers is lower because they also benefit from a statue of repose in their home market. The Association of Manufacturing Technology has noted, for example, that the price of imported products can be lower due to

³⁷ *Id.* at 1.

³⁸ Testimony of Dr. Malcolm Skolnick, April 5, 1990 hearing, S. Hrg. 101-743 at 300 (1990).

³⁹ See Jon Cohen, "Is Liability Slowing AIDS Vaccines?," *Science*, Apr. 10, 1992, at 168-69.

⁴⁰ *The Liability Maze* at 343.

⁴¹ The Conference Board Report at 4 (citing a 1984 study commissioned by the U.S. Department of Commerce).

⁴² *Id.*

⁴³ See Orban, *Product Liability and International Trade and Policies*, *Product Liability and Tort Law Reform*, National Legal Center for the Public Interest, 144 (April 21, 1982).

the difference in liability insurance rates, if the importer does not sell all of its products in the United States.⁴⁴

Changes in conflict of law theory also have added to the competitive disadvantage faced by American firms. An individual, injured in a foreign country by a U.S. product, now may be able to sue the manufacturer in the United States and have U.S. law applied in the case. In the past, the rule of *lex loci* would have required the application of the foreign country's law.⁴⁵ The diminished importance of *lex loci* means U.S. manufacturers may be held to higher and more costly product liability standards in both U.S. and foreign markets while foreign competitors only confront U.S. law in the United States.

Professor Aaron Twerski testified in 1991 that "uncontrolled damages have serious international implication(s)" because the United States has been unable to get foreign countries to enter into treaties to enforce American judgments abroad due to "unregulated judgments."⁴⁶ American businesses suffer as a result when they are unable to enforce overseas simple money judgments.⁴⁷

E. PRODUCT LIABILITY AND PRODUCT SAFETY

Those who oppose product liability reform believe the product liability system, as presently constructed, promotes safety. They argue alterations to the system will enable unsafe products to enter the market. Most often, those opposing reform argue that unbounded punitive damages are the threat that makes products safer.⁴⁸

There is a notable lack of evidence for these assertions. William Fry, the Executive Director of HALT, testified at the April 3, 1995 hearing that some states and foreign countries such as Canada do not have punitive damages yet "there is no evidence that product liability suits there do not achieve changes in conduct."⁴⁹ Fry noted that "[f]or most defendants the stigma of punitive damages motivates reform" because excessive punitive damages are usually overturned on appeal.⁵⁰

In his testimony on April 4, 1995, Professor M. Stewart Madden indicated that, in a punitive damage award, "the public finding of rogue conduct can be as great a punishment, and as much a deterrent to the defendant and to other marketplace participants, as the punitive monetary award."⁵¹ Professor Madden explained "[t]here is overwhelming evidence...that manufacturers are alert to public

⁴⁴ Letter from James A. Gray, President, National Machine Tool Builders Association, to Jim J. Tozzi, Deputy Director of Information and Regulatory Affairs, Office of Management and Budget (June 14, 1982). The letter also points out the effect of the lack of a statute of repose on this industry. AMT indicates there are cases in which 50-year old products have been the subject of product liability lawsuits.

⁴⁵ Testimony of Professor Aaron Twerski, September 19, 1991 hearing, S. Hrg. 102-727 at 101-102 (1991); See *Pray v. Lockheed Aircraft Corp.*, 644 F. Supp. 1289 (D.D.C. 1986) (Washington, D.C. law applied in lawsuit against U.S. manufacturer for damages arising outside Saigon, Vietnam).

⁴⁶ Testimony of Professor Aaron Twerski, September 19, 1991 hearing, S. Hrg. 102-727 at 105.

⁴⁷ *Id.*

⁴⁸ See e.g., Testimony of Larry Stewart, President of the Association of Trial Layers of America, April 3, 1995 hearing, S. Hrg. 104-435 at 138.

⁴⁹ Testimony of William Fry, April 3, 1995 hearing, S.Hrg. 104-435 at 88.

⁵⁰ *Id.*

⁵¹ Testimony of M. Stuart Madden, April 4, 1995 hearing, S.Hrg. 104-435 at 366.

opinion as to their behavior.”⁵² He also noted a punitive damage award will ensure that state and federal regulators descend on a defendant and thus assure they modify their conduct.⁵³

The editors of *The Liability Maze* also concluded that factors other than the product liability system—such as safety regulations—are responsible for the promotion of safety.⁵⁴ For example, Professor John Graham of the Harvard University School of Public Health, conducted five case studies on whether there was a relationship between motor vehicle safety and product liability law. He concluded “[t]he case studies provide little evidence that expanded product liability risk was necessary to achieve the safety improvements that have been made.”⁵⁵ Instead, Graham concluded vehicle safety regulation can provide a predictable and technically sound forum in which to resolve safety issues.⁵⁶

The safety benefits of product liability reform are evidenced in the General Aviation Revitalization Act, signed into law by President Clinton on August 17, 1994, which established a uniform, national statute of repose of 18 years for noncommercial general aviation aircraft. Opponents of product liability reform opposed that Act on the grounds that it would lead to the production of less safe aircraft. Quite the contrary has occurred. As the Act’s proponents contended, the safety of general aviation aircraft has already improved as new, more advanced and safer component systems have been introduced into the general aviation market. The Act also enhanced safety because it fostered the domestic production of new, more modern general aviation aircraft.

F. BIOMATERIALS

There is an emerging crisis in the supply of biomaterials used in the production of implantable medical devices. Suppliers of raw materials and component parts are reluctant to sell to medical device manufacturers because, under current litigation practice, those suppliers are routinely sued with device manufacturers in actions alleging inadequate design and testing of the medical device and inadequate warnings related to the use of the medical device. Biomaterials suppliers, however, do not design, produce or test medical devices. Consequently, it is rare that biomaterials suppliers ultimately are held liable in these actions.

Nonetheless, suppliers of biomaterials are reluctant to sell to medical device manufacturers because the costs of successfully defending themselves exceed the expected return from supplying the biomaterials. The biomaterials suppliers provide raw materials and component parts that are not designed or manufactured specifically for use in medical devices: these materials also are used in a variety of nonmedical products. As a result, supplying materials for medical devices is a very small portion of their business and is easily foregone to avoid the cost of successfully defending liability suits.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ See *The Liability Maze* at 12–13.

⁵⁵ “Product Liability and Motor Vehicle Safety” in *The Liability Maze* at 183–184.

⁵⁶ *Id.* at 184.

Ms. Peggy Phillips, an attorney with a life-sustaining medical device, testified before the Subcommittee on April 4, 1995, that in the current climate it did not make sense for biomaterials suppliers to continue providing those materials for device manufacturers. Ms. Phillips related that one supplier spent \$8 million annually defending itself in cases involving temporomandibular joint (TMJ) implants even though that supplier had no role in the design, manufacture or sale of the device. Ms. Phillips noted sales by all suppliers to all TMJ implant manufacturers "totaled \$418,000 while sales of this same raw material to all other markets totaled \$282 million."⁵⁷ In essence, biomaterials suppliers will not provide their product to medical device manufacturers because such transactions involve low returns and a high risk of substantial losses.

Millions of Americans, who rely on life-saving or life-enhancing medical devices, face a potentially devastating health crisis if reforms are not instituted. For example, Tara Ransom, a nine-year old from Phoenix, Arizona, is alive today because a brain shunt (a plastic tube) relieves a severe medical condition called hydrocephalus that causes excess fluid to build around the brain.⁵⁸ Children outgrow these shunts so they periodically need to be replaced, often in emergency procedures. Tara, and numerous other children, may not be able to have this medical device replaced, because companies that supplied basic materials for the medical device will no longer do so. Congressional action is urgently needed to avoid such tragedies.

III. FEDERAL REFORM IS REQUIRED AS STATE REFORM IS INHERENTLY LIMITED

Those opposing product liability reform argue, that if reform is desirable, it is the domain of the states.⁵⁹ Reform is desirable, it is urgently needed, and given the nature and scope of the problem, only federal reform can be effective.

Reform by the states can do little to resolve the tort litigation problems facing those who deal in an interstate market. Products are manufactured, sold, used, and insured in a nationwide market. Data show the vast majority of products manufactured in a given state are consumed or used outside that state.⁶⁰ As a result, manufacturers and product sellers may be involved in product liability actions governed by the law of any state in which they do business. Thus, an attempt by any one state to reform the system cannot re-

⁵⁷Testimony of Peggy Phillips, April 4, 1995 hearing, S.Hrg. 104-435 at 205.

⁵⁸See Linda Ransom, *Lawyers May Kill My Daughter*, *The Wall St. J.*, March 20, 1996.

⁵⁹See e.g. Testimony of Jeffrey Teitz, representing The National Conference of State Legislatures, April 3, 1995 hearing, S.Hrg. 104-435 at 57; Testimony of Larry Stewart, President of The Association of Trial Lawyers of America, April 3, 1995 hearing, S.Hrg. 104-435 at 142.

⁶⁰Testimony of the Honorable Wendell L. Wilkie II, General Counsel, U.S. Department of Commerce, April 5, 1990 hearing, S. Hrg. 101-743 at 48 (1990). It has been estimated 30.5 percent of manufactured goods are consumed in the manufacturing state. See, 1977 Census of Transportation, Commodity Transportation Survey, Summary, U.S. Dept. of Commerce, Bureau of the Census, 1-77 (1981); American Bar Assoc. Section of Corporation, Banking and Business Law, Report to the House of Delegates, Attachment B. (1982). See generally Testimony of Randolph J. Stayin on behalf of the American Textile Machinery Association, Product Liability Act: Hearing before the Subcommittee on Consumer of the Senate Committee on Commerce, Science, and Transportation, 99th Cong., 1st Sess., Rept. No. 99-84, 170 (1985).

lieve the overall burden imposed on interstate commerce.⁶¹ Insurers recognized this fact years ago and set liability insurance rates based on national data rather than on state data.

The National Governor's Association (NGA) has long recognized both the need for product liability reform and the necessity of federal action to effectuate that reform. As Governor of Arkansas, President Clinton was twice a member of NGA committees that drafted and unanimously approved resolutions calling for federal product liability reform.

NGA's Director of State-Federal Relations, James Martin, testified before the Subcommittee on April 3, 1995 concerning the NGA's advocacy for federal product liability reform. Mr. Martin indicated that in 1982, the NGA opposed preemption of state law, but by 1986 this position was unanimously reversed to support uniform federal product liability laws.

Mr. Martin testified the NGA "traditionally has opposed federal preemption unless there are highly compelling reasons to justify federal actions that require changes in policies adopted by state officials."⁶² The Governors believe those conditions exist in the area of product liability.

On February 7, 1997 the NGA unanimously approved a resolution calling for product liability reform undertaken by the federal government. The resolution adopted, by the NGA provides an excellent summary of the need for reform executed on the federal level. That resolution reads, in part, as follows:

The National Governors' Association recognizes that the current patchwork of U.S. product liability laws is too costly, time-consuming, unpredictable, and counter productive, resulting in severely adverse effects on American consumers, workers, competitiveness, innovation and commerce.

The issue of product liability reform has increasingly pointed to federal action as a way to alleviate the problems faced by small and large businesses with regard to inconsistent state product liability laws. This lack of uniformity and predictability makes it impossible for product manufacturers to accurately assess their own risks, leading to the discontinuation of necessary product lines, reluctance to introduce product improvements, and a dampening of product research and development. American small businesses are particularly vulnerable to disparate product liability laws. For them, liability insurance coverage has become increasingly expensive, difficult to obtain, or simply unavailable. Further, the system causes inflated prices for consumer goods and adversely affects the international competitiveness of the United States.

Clearly, a national product liability code would greatly enhance the effectiveness of interstate commerce. The Governors urge Congress to adopt a federal uniform product liability code.⁶³

⁶¹ Several state governors have recognized this in vetoing proposed product liability legislation. See, e.g., Victor Schwartz and Barbara Bares, *Federal Reform of Product Liability Law: A Solution That Will Work*, 13 Cap. U. L. Rev. 351, 355 (1984).

⁶² Testimony of James Martin, April 3, 1995 hearing, S.Hrg. 104-435 at 26.

⁶³ NGA policy EDC-15 (1997).

Kirk Dillard, a State Senator from Illinois, testified in April 1995, that the American Legislative Exchange Council (ALEC) strongly advocates states' rights but nevertheless supports enactment of federal product liability legislation.⁶⁴ ALEC is a bipartisan organization of approximately 3,000 state legislators from all 50 states. Mr. Dillard indicated federal action is needed because "virtually all business transactions have an interstate commerce component, subjecting companies to suits in numerous different states."⁶⁵

Professor Madden testified "products liability law cries out for uniformity."⁶⁶ Only federal legislation can create the uniformity necessary to relieve the enormous burdens imposed by the existing product liability system. Congress clearly has the power, under the interstate commerce clause of the United States Constitution, to enact reform.⁶⁷ In the past, Congress has preempted state tort law when diverse state laws burdened interstate commerce.⁶⁸

A clear articulation of the need for federal product liability reform is found in *Garnes v. Fleming Landfill, Inc.*⁶⁹ The West Virginia Supreme Court stated, in an opinion drafted by the Chief Justice, Richard Neely, that, as to product liability:

State courts have adopted standards that are, for the most part, not predictable, not consistent and not uniform. Such fuzzy standards inevitably are most likely to be applied arbitrarily against out-of-state defendants. Moreover, this is a problem that state courts are by themselves incapable of correcting regardless of surpassing integrity and boundless goodwill. State courts cannot weigh the appropriate trade-offs in cases concerning the national economy and national welfare when these trade-offs involve benefits that accrue outside the jurisdiction of the forum and detriments that accrue inside the jurisdiction of the forum.

Product liability reform must occur at the federal level because reform undertaken at the state level, either by courts or by legislatures, cannot address fully the problems with our product liability system.

LEGISLATIVE HISTORY

S. 648 was introduced on April 24, 1997 by Senators Gorton, Ashcroft, McCain, Lott and Abraham. Although S. 648 is similar to S. 5, which bears the same title, there are important differences. S. 5 was introduced on January 21, 1997, by Senators Ashcroft, McCain and Lott. The text of the of S. 5 is identical to that of the

⁶⁴ Testimony of Kirk W. Dillard, April 3, 1995 hearing, S.Hrg. 104-435 at 32.

⁶⁵ *Id.* at 4.

⁶⁶ Testimony of M. Stuart Madden, April 4, 1995 hearing, S.Hrg. 104-435 at 376.

⁶⁷ U.S. Const., Art. I, Sec. 8, cl. 3.

⁶⁸ Congress preempted state tort reform to promote the nuclear power industry. See *Duke Power Co. v. Carolina Environmental Study Group*, 439 U.S. 59 (1978). See also Public Utility Holding Company Act of 1935, 15 U.S.C. sec. 79 et seq. (activities involved "not susceptible of effective control by any State"); United States Cotton Standards Act, 7 U.S.C. sec. 51 et seq. (uniform national classifications necessary to protect and promote commerce); Cigarette Labeling and Advertising Act, 15 U.S.C. sec. 1331 et seq. (national standards essential in order that "commerce and the national economy...not (be) impeded by diverse, nonuniform regulations"); Federal Employers' Liability Act, 45 U.S.C. 51 et seq.

⁶⁹ 413 S.E.2d 897, 905 (W. Va. 1991).

Conference Report of the product liability bill from the 104th Congress. That Conference Report was vetoed by President Clinton.

On March 4, 1997 Senator McCain chaired a Committee hearing on product liability reform. On March 6, 1997, Senator Ashcroft chaired a hearing of the Subcommittee on Consumer Affairs, Foreign Commerce and Tourism to explore the success of the General Aviation Revitalization Act of 1994. That bill provided a statute of repose for general aviation aircraft.

The Committee on Commerce, Science and Transportation favorably reported S. 648 by a roll call vote of 11 to 9.

The Committee has a long history of involvement with product liability reform. In the Committee's early treatment of the subject, it reported three bills, each of which was introduced by Senator Kasten. S. 2631 was reported by the Committee in the 97th Congress (S. Rep. 97-670), and S. 44 was reported by the Committee in the 98th Congress (S. Rep. 98-476). Congress adjourned without Senate action on either of these measures.

At the beginning of the 99th Congress, on January 3, 1985, Senator Kasten introduced S. 100, the Product Liability Act. This bill preempted state law to impose uniform federal rules and standards of liability governing the recovery of damages for injuries caused by defective products. The legislation was substantially the same as S. 44, which had been reported by the Committee during the 98th Congress.

A Consumer Subcommittee hearing on S. 100 was held on March 21, 1985 (Serial No. 99-84) and the bill was reviewed by the Committee at an executive session on May 16, 1985. At that session, the motion to report the bill was defeated by an 8-8 vote.

Prior to the May 16, 1985 executive session, two amendments in the nature of a substitute to S. 100 had been introduced. One of these amendments (S. Amdt. No. 16) was introduced by Senator Dodd on March 19, 1985, and the other (S. Amdt. No. 100) was introduced by Senator Gorton on May 14, 1985. These amendments were complete substitutes for S. 100 that preempted certain aspects of state law and also established alternative expedited claim systems for limited recovery of damages in product liability cases. Hearings on the Dodd and Gorton amendments were held by the Consumer Subcommittee on June 18 and June 25, 1985 (Serial No. 99-177).

After these hearings, the Committee staff was instructed by the Chairman of the Commerce Committee, Senator Danforth, to draft a proposal that combined elements of all these measures. After review of extensive comments received from the public in connection with the Committee's first draft, a second draft was released on November 20, 1985. This draft was formally introduced by Senator Danforth on December 20, 1985, as S. 1999. This bill was the subject of two days of hearings before the Consumer Subcommittee on February 27 and March 11, 1986.

On April 30, 1986, Senator Kasten introduced an amendment in the nature of a substitute for S. 100 (S. Amdt. No. 1814).⁷⁰ This amendment embodied recommendations for product liability reform

⁷⁰ 132 Cong. Rec. S5106.

that had been made by the administration's Tort Policy Working Group.⁷¹

On May 12, 1986, Senator Danforth introduced an amendment in the nature of a substitute for S. 1999 (S. Amdt. No. 1951).⁷² This amendment replaced the expedited claim system of S. 1999 with an expedited settlement system and made a number of other changes in S. 1999. On May 20, 1986, Senator Gorton introduced an amendment in the nature of a substitute to the Danforth amendment (S. Amdt. No. 1968).⁷³ On May 19 and 20, 1986, the Consumer Subcommittee held hearings on the Kasten amendment, the Danforth amendment, and the other product liability measures before the Committee.

On June 3, 1986, the Committee began its markup of product liability legislation. The markup draft bill was an original bill that embodied the provisions of the Danforth amendment to S. 1999. On June 12, the Committee adopted an amendment in the nature of a substitute for the original markup draft bill. On June 12, 19, 24, 25 and 26, 1986, the Committee continued its consideration of the amendment and added a number of other amendments before reporting S. 2760 as an original bill. S. 2760 came before the full Senate on September 17, 1986. On September 25, the Senate agreed to the motion to proceed to S. 2760 by a vote of 84 to 13. The bill was returned to the Senate Calendar, and no further action was taken.

The primary activity on federal product liability legislation in the 100th Congress occurred in the House of Representatives. On February 18, 1987, Congressmen Bill Richardson and Thomas A. Luken introduced H.R. 1115, which was referred to the House Energy and Commerce Committee. The Subcommittee on Commerce, Consumer Protection and Competitiveness held extensive hearings on the need for federal product liability reform and on specific issues in the bill on May 5, May 20, June 18, July 21, August 6, October 7, and December 17, 1987. The Subcommittee met to mark up the bill on November 18, 19, and 20, and December 3 and 8, 1987. H.R. 1115 was reported by the Subcommittee, as amended, on December 8, 1987, by a vote of 11 to 3. On May 10, 12, 18, 19, and 24, June 1, 2, 8, 9, and 14, 1988, the Energy and Commerce Committee met to mark up H.R. 1115, voting on June 14 to report H.R. 1115, as amended, favorably by a recorded vote of 30 to 12. H.R. 1115 then received a sequential referral to the House Committees on the Judiciary and on Education and Labor. The Education and Labor Committee held a hearing on September 27, 1988, on provisions in H.R. 1115 that affected workplace safety. The House Judiciary Committee took no action on the bill in the 100th Congress. The sequential referral ran through the end of the session, so the 100th Congress adjourned without considering H.R. 1115 on the floor of the House.

During the 101st Congress, the Committee held three hearings on S. 1400, the Product Liability Reform Act, introduced by Senator Kasten (S. Hrg. 101-243). On May 22, 1990, the Commerce

⁷¹ Report of the Tort Policy Working Group on the Causes, Extent and Policy Implications of the Current Crisis in Insurance Availability and Affordability (February 1986).

⁷² 132 Cong. Rec. S5874.

⁷³ 132 Cong. Rec. S6232.

Committee reported an amendment in the nature of a substitute to S. 1400 by a roll call vote of 13 to 7 (S. Rep. 101-356). The full Senate took no action before the adjournment of the 101st Congress.

In the 102nd Congress, Senator Kasten introduced S. 640 on March 13, 1991. There were 36 cosponsors of the bill, including seven members of the Committee. On September 12, 1991, the Consumer Subcommittee held a hearing on S. 640 and the full Commerce Committee held a second day of hearings on S. 640 and S. 645, The General Aviation Accident Standards Act of 1991, on September 19, 1991. On October 3rd, the Committee favorably reported S. 640 by a roll call vote of 13 to 7.

On May 7, 1992, the provisions of S. 640 were incorporated into an amendment offered by Senator Kasten to S. 250, the National Voter Registration Act. On May 14, the amendment was tabled by a vote of 53 to 45. On June 26, the bill was sequentially referred to the Committee on the Judiciary until August 12. The Judiciary Committee held a hearing on August 5th but took no further action. Under the terms of a unanimous consent agreement, on September 8, the Senate began consideration of a motion to proceed to consider S. 640. On September 10, the Senate failed to invoke cloture on the motion to proceed by a vote of 57 to 39. A motion to reconsider that vote was agreed to by a vote of 57 to 39, and a subsequent cloture vote failed 58 to 38. No further action was taken.

In the 103rd Congress, Senators Rockefeller and Gorton introduced S. 687, The Product Liability Fairness Act, on March 31, 1993. The Consumer Subcommittee held a hearing on S. 687 on September 23, 1993 (S. Hrg. 103-490). On November 9, 1993 the Committee ordered S. 687 favorably reported by a roll call vote of 16 to 4. The bill was taken to the floor and on June 28, 1994 a motion to invoke cloture failed 54 to 44. On June 29, 1994 a second motion to invoke cloture failed 57 to 41.

In the 104th Congress, Senators Jay Rockefeller and Slade Gorton introduced, on March 15, 1995, S. 565, the Product Liability Fairness Act. On March 10, 1995, the House of Representatives had passed legislation, H.R. 956, the Common Sense Product Liability and Legal Reform Act of 1995, by a vote of 265 to 161. On April 3 and 4, 1995, the Subcommittee on Consumer Affairs, Foreign Commerce and Tourism held hearings on S. 565 (S.Hrg. 104-435). At the Committee executive session on April 6, 1995, the Chairman of the Commerce Committee, Senator Pressler, offered an amendment in the nature of a substitute that maintained the original content of S. 565 but, among other things, incorporated as Title II, S. 303, The Biomaterials Access Assurance Act. S. 303 was introduced by Senators Lieberman and McCain on January 31, 1995, and was referred to the Commerce Committee. On April 6, 1995, the Senate Committee on Commerce, Science, and Transportation favorably reported S. 565 as amended by the Chairman's mark by a roll call vote of 13 to 6 (S. Report 104-69). The bill was taken up by the Senate on April 24, 1995 and was approved by a vote of 61 to 37 on May 10, 1995.

A Conference Report, H.R. 956 the Common Sense Product Liability and Legal Reform Act of 1996 was issued on March 14, 1996. The conference report was very similar to the bill originally

passed by the Senate. The Senate approved the conference report by a vote of 59 to 40 on March 21, 1996. The House of Representatives passed the Conference Report on March 29 by a vote of 259 to 158. The President vetoed the bill on May 2, 1996.

SUMMARY OF MAJOR PROVISIONS

The major provisions of S. 648 are summarized below in the order they appear in the bill.

A. TITLE I: PRODUCT LIABILITY REFORM

1. *Section 102: Applicability; preemption*

The Act applies to any product liability action filed on or after the Act's date of enactment. The Act preempts State law only to the extent that State law applies to an issue covered in the Act. If an issue is not covered in the bill state law is not preempted on that point.

2. *Section 103: Liability rules applicable to product sellers, renters, and lessors*

Product sellers are held liable only for their own negligence or failure to comply with an express warranty. The product seller, however, remains liable as if it were the manufacturer if the manufacturer cannot be brought into court or is unable to pay a judgment. This provision assures injured persons will always have available an avenue for recovery.

3. *Section 104: Defense based on claimant's use of intoxicating alcohol or drugs*

The defendant has a complete defense if the plaintiff was under the influence of intoxicating alcohol or illegal drugs and as a result of this influence was more than 50 percent responsible for the plaintiff's injuries.

4. *Section 105: Misuse or alteration*

A defendant's liability is reduced to the extent a claimant's harm is due to the misuse or alteration of a product.

5. *Section 106(a): Statute of Limitations*

The statute of limitations is established as two years from when the claimant discovered or should reasonably have discovered both the harm and its cause. This "discovery rule" for the statute of limitations will assure that potential plaintiffs have a fair opportunity to bring suit.

6. *Section 106(b): Statute of Repose*

A statute of repose of 18 years is established for product liability lawsuits. After 18 years or longer, no suit may be filed for injuries related to their use unless the defendant made an express warranty in writing as to the safety of the specified product involved, and the warranty was longer than the period of repose (18 years). In such situations, the statute of repose does not apply until that warranty period is complete. The statute of repose does not apply in cases involving toxic harm.

7. Section 107: Alternative dispute resolution procedures

Either party may offer to participate in a voluntary, non-binding state-approved alternative dispute resolution (ADR) procedure.

8. Section 108: Uniform standards for award of punitive damages

Punitive damages may be awarded if a plaintiff proves, by “clear and convincing evidence,” that his or her harm was caused by the defendant’s “conscious, flagrant indifference to the safety of others.”

Punitive damages may be awarded up to two times compensatory damages or \$250,000 whichever is greater. The judge is permitted to award punitive damages beyond this limit after considering certain factors, but the judge cannot exceed the amount of the jury’s original award.

When the defendant is a small business (or similar entity) with less than 25 full-time employees, punitive damages may not exceed \$250,000 or two times compensatory damages, whichever is less. When a small business is the defendant, the judge is not permitted to award punitive damages above this limit as the judge may when a big business is the defendant.

Either party can request the trial be conducted in two phases, one dealing with compensatory damages and the other dealing with punitive damages. The same jury is used in both phases.

9. Section 109: Liability for Certain Claims Relating to Death

This provision gives Alabama the opportunity to change its unique laws that provide that only punitive damages are available in a wrongful death action. Since Alabama uses this terminology the punitive damage provisions of the bill would apply to wrongful death actions not just to product liability actions as intended.

10. Section 110: Several Liability for Noneconomic Damages

Joint liability is abolished for noneconomic damages, such as pain and suffering. As to these damages, defendants are liable only in direct proportion to their responsibility for the claimant’s harm.

B. TITLE II: BIOMATERIALS ACCESS ASSURANCE

The Biomaterials Access Assurance Act would allow suppliers of the raw materials and component parts (“biomaterials”) used to make medical implants, to obtain dismissal, without extensive discovery or other legal costs, in certain tort suits in which plaintiffs allege harm from a finished medical implant.

The Act would not affect the ability of plaintiffs to sue manufacturers or sellers of medical implants. It would, however, allow raw materials suppliers to be dismissed from lawsuits if the generic raw material used in the medical device met contract specifications, and if the biomaterials supplier cannot be classified as either a manufacturer or seller of the medical implant.

1. Section 201: Short Title

This section states the short title of the bill: the “Biomaterials Access Assurance Act of 1997.”

2. Section 202: Findings

This section contains the findings upon which the bill is based. A health care crisis is developing because the supply of medical devices is at risk. Many raw materials suppliers are now reluctant to sell their products to medical device manufacturers because of possible exposure to product liability suits.

3. Section 203: Definitions

Various terms used in Title II are defined.

Litigation concerning silicone gel breast implants is excluded from the bill. This is accomplished by excluding such plaintiffs from the definition of “claimant” (section 203(2)(D)(iii)).

4. Section 204: General Requirements; applicability; preemption

This section specifies that, in any civil action covered by the bill, a biomaterials supplier may raise any defense set forth in section 205, and the court must use the procedures set forth in section 206 in connection with that defense.

Section 204 states that the bill applies to any civil action brought by a claimant in Federal or State court against a manufacturer, seller, or biomaterials supplier, on the basis of any legal theory, for harm allegedly caused by an implant.

Section 204 states that the bill preempts State law to the extent the bill establishes a rule of law.

This section also states that the bill may not be construed to affect any defense available to a defendant under other provisions of law in an action alleging harm caused by an implant.

5. Section 205: Liability of biomaterials suppliers

This section restricts the liability of biomaterials suppliers in lawsuits covered by the bill to three situations, where the supplier: (I) was itself the manufacturer of the implant; (ii) was itself the seller of the implant; or (iii) furnished raw materials that failed to meet applicable contractual requirements or specifications.

A supplier may be deemed to be a manufacturer only if the supplier registered as such with the FDA pursuant to medical device requirements or if the Secretary of HHS issues a declaration that the supplier should have registered as such. Section 205 also establishes a procedure for the Secretary to issue such a declaration.

A supplier may be deemed to be a seller and thus liable in situations in which the supplier itself resold the implant after it had been manufactured and had entered the stream of commerce.

With respect to contractual requirements, a supplier may be liable for harm only if the claimant shows that the biomaterials were not the actual product for which the parties contracted or the biomaterials failed to meet certain specifications and that failure was the cause of the injury. The relevant specifications are those: (I) provided to the supplier by the manufacturer; (ii) provided by the manufacturer (either published, given to the manufacturer, or included in an FDA master file); or (iii) included in manufacturer submissions that had received clearance from the FDA.

6. Section 206: Procedures for dismissal of civil actions against bio-materials suppliers

Subsection (a) establishes a new procedure for dismissal of lawsuits against suppliers. A supplier named as a defendant or joined as a co-defendant may file a motion for dismissal based on the defenses set forth in section 205.

Subsection (b) requires that a plaintiff sue a manufacturer directly whenever jurisdiction over the manufacturer is available.

Subsection (c) establishes procedural requirements for the proceeding on a motion to dismiss. A motion on the ground that the supplier is not a manufacturer would be automatically granted if the supplier had not filed with the FDA as a manufacturer of the implant unless the plaintiff obtained a ruling from the FDA that the supplier should have registered as a manufacturer. A ruling on the supplier's pretrial motion for dismissal is based solely on the pleadings and any affidavits.

If the pleadings and affidavits raise genuine issues of material facts with respect to a motion concerning compliance with contractual requirements and specifications, the court may treat the motion for dismissal as a motion for summary judgment in accordance with section 206(d).

Discovery is limited to establishing whether an issue of material fact exists. The court would grant the summary judgment motion unless the plaintiff has submitted evidence sufficient to allow a jury to reach a verdict for the plaintiff.

Subsections (f) and (g) change other procedural aspects to reduce the litigation burdens. The manufacturer, not the supplier, may conduct the proceeding on the motion if an appropriate contractual indemnification agreement exists. The possibility of frivolous claims against a supplier is reduced by permitting the court to require the plaintiff to pay attorney fees if the plaintiff succeeds in making the supplier a defendant, but ultimately is found to have a meritless claim.

C. TITLE III: LIMITATIONS ON APPLICABILITY; EFFECTIVE DATE

1. Section 301: Effect of court of appeals decisions

A decision by a Federal circuit court of appeals concerning this Act is deemed a controlling precedent for any Federal or State court within the geographical boundaries of the area under the jurisdiction of the circuit court of appeals.

2. Section 302: Federal cause of action precluded

Federal district courts are precluded from jurisdiction pursuant to sections 1331 or 1337 of title 28, United States Code.

3. Section 303: Effective Date

The Act applies to any action filed on or after the date the legislation is enacted.

ESTIMATED COSTS

In accordance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate and Section 403 of the Congressional Budget

Act of 1974, the Committee provides the following cost estimate, prepared by the Congressional Budget Office:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 14, 1997.

Hon. JOHN MCCAIN,
Chairman, Committee on Commerce, Science, and Transportation,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 648, the Product Liability Reform Act of 1997.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Susanne S. Mehlman (for federal costs), and Pepper Santalucia (for the state and local impacts).

Sincerely,

JAMES L. BLUM
(For June E. O'Neill, Director).

Enclosure.

S. 648—Product Liability Reform Act of 1997

CBO estimates that enacting the bill would have no significant effect on the federal budget. Because the bill would not affect direct spending or receipts, pay-as-you-go procedures would not apply. The bill contains intergovernmental mandates as defined in the Unfunded Mandates Reform Act of 1995 (UMRA), but CBO estimates that the net costs of complying with those mandates would be well below the threshold established in the law (\$50 million in 1996, adjusted annually for inflation). This bill would impose no new private-sector mandates as defined in UNRA.

S. 648 would set new standards for product liability cases and would limit the amount of punitive damages that may be awarded to a plaintiff to two times the plaintiff's compensatory damages or \$250,000 whichever would be larger. However, if the defendant is a small business, any punitive damages awarded would be capped at \$250,000. The new standards included in S. 648 would determine when the seller of a product or the supplier of biomaterials (raw materials used to make medical implants) is liable for damages and when a defense based on a claimant's use of drugs or alcohol could be used. S. 648 also would abolish joint liability for noneconomic damages and would enable private parties to use alternative dispute resolution procedures to settle product liability cases. In addition, the bill would prohibit the filing of a lawsuit unless the complaint is filed within two years from when the injured party discovered, or should reasonably have discovered, the alleged harm and its cause as long as this period for discovery does not exceed 18 years from when the product was first sold.

While some product liability cases may be tried in federal court, the majority of such cases are handled in state courts. Based on information from the Administrative Office of the United States Courts, CBO estimates that enacting this bill would have no significant impact on the number of cases that would be referred to

federal courts. Thus, we estimate that enacting S. 648 would have no significant impact on the federal budget.

The bill contains intergovernment mandates as defined in UMRA because it would preempt state laws in setting national standards for product liability cases. States could initially incur some costs in adjusting to the new national standards. Based on information from the National Center for State Court, CBO estimates that those cost would be well below the threshold established in the law (\$50 million in 1996, adjusted annually for inflation). In the longer run, states could realize net savings if this bill were to discourage potential plaintiff from filing product liability suits.

In addition, the bill would limit punitive damage award against local governments in product liability cases to no more than \$250,000. This provision could result in savings to individual localities, but based on the number of punitive damage awards in recent years CBO estimates that aggregate savings to all localities nationwide would not be significant.

The CBO staff contacts are Susanne S. Mehlman (for federal costs), and Pepper Santalucia (for the state and local impact). This estimate was approved by Robert A. Sunshine, Deputy Assistant Director for Budget Analysis.

REGULATORY IMPACT STATEMENT

In accordance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee provides the following evaluation of the regulatory impact of the legislation, as reported.

NUMBER OF PERSONS AFFECTED

The purpose of this product liability reform legislation, as reported, is to provide greater certainty as to the rights and responsibilities of all those involved in product liability disputes, to reduce transaction costs, to relieve the burden imposed on interstate commerce by the present product liability litigation system, and to ensure the continued availability of biomaterials for implantable medical devices. It is anticipated that it will affect the conduct of those involved in product liability disputes by making a number of significant changes in the laws that are applicable to all product liability actions. This legislation does not change the jurisdiction of state or federal courts. Thus, the number of persons affected should be consistent with current levels.

ECONOMIC IMPACT

It is anticipated that this legislation will result in substantial cost and paperwork savings to all parties affected by product liability lawsuits. First, the legislation will bring greater predictability to this area of the law, and, thus, save time and money for manufacturers, product sellers and consumers alike, each of whom will be able to determine their rights more readily than under current law. The legislation should also foster product innovation and enhance the competitive position of U. S. product manufacturers in world markets.

PRIVACY

S. 648 will have no adverse impact on the personal privacy of the individuals or businesses affected.

PAPERWORK

S. 648 creates no new regulations and imposes no additional regulatory requirements at either state or the federal level. The legislation will not change the jurisdiction of state or federal courts.

SECTION-BY-SECTION ANALYSIS OF S. 648

Section 1—Short title and table of contents

Section 1(a) identifies the short title of the legislation as the “Product Liability Reform Act of 1997” (the “Act”). Section 1(b) sets forth the Table of Contents to the Act.

Section 2—Findings and purposes

Section 2 contains the “Findings” of Congress and the “Purposes” of the Act.

TITLE I—PRODUCT LIABILITY

Section 101—Definitions

Section 101 defines terms or phrases used in the Act.

Section 101 defines the following terms:

(1) ACTUAL MALICE.—The term means specific intent to cause serious physical injury, illness, disease, death, or damage to property.

(2) CLAIMANT.⁷⁴—As used in this title, the term means any person who brings a product liability action and any person on whose behalf such an action is brought.⁷⁵ If a product liability action is brought through or on behalf of an estate, the term includes the claimant’s decedent. If a product liability action is brought through or on behalf of a minor, the term includes the minor’s legal guardian.

(3) CLEAR AND CONVINCING EVIDENCE.—The phrase means that measure or degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established. The “clear and convincing evidence” standard reflects the quasi-criminal nature of punitive damages; it requires proof greater than the “preponderance of the evidence” standard ordinarily used in civil cases, but less proof than the “beyond a reasonable doubt” standard found in the criminal law.

(4) COMMERCIAL LOSS.—The term means any loss or damage solely to a product itself, loss relating to a dispute over its value, or consequential economic loss, the recovery of which is governed by the Uniform Commercial Code or analogous state commercial or contract law.

⁷⁴The Act does not alter or preempt State law governing who may be a “claimant.” For example, state statutes governing who may bring a wrongful death or survival action are not affected by the Act. Such persons, if authorized by State law to bring the action, are “claimants” under the Act.

⁷⁵Title II of the Act also contains a definition for the term “claimant.” See section 203(2). The definition found in section 203(2) is to be applied in actions governed by that Title.

(5) **COMPENSATORY DAMAGES.**—The term means damages awarded for economic and noneconomic loss.

(6) **ECONOMIC LOSS.**—The term means any pecuniary loss resulting from harm, including any medical expense, work loss, replacement services loss, loss due to death, burial costs, and loss of business or employment opportunities, to the extent recovery for such loss is allowed under applicable state law.

The essential distinction between economic and noneconomic loss is that economic loss is subject to empirical measurement and confirmation. In contrast, noneconomic loss, such as “pain and suffering,” is not capable of measurement according to an objective standard.⁷⁶

(7) **HARM.**—The term is defined to include any physical injury, illness, disease, or death, or damage to property caused by a product.⁷⁷ Whether the harm is suffered by an individual or a business is of no consequence; it is the nature of the loss that triggers application of the Act. The Act leaves recovery for commercial losses to commercial law, in accord with the traditional rule followed in the overwhelming majority of states.⁷⁸

(8) **MANUFACTURER.**—The term is defined as (A) any person who is engaged in a business to produce, create, make, or construct any product (or component part of a product), and who (I) designs or formulates the product (or component part of the product), or (ii) has engaged another person to design or formulate the product (or component part of the product).⁷⁹ The term does not include a person who only designs or formulates a product—such as an architect or engineer. These persons, although not liable under the Act, may be liable under traditional tort law for failure to exercise reasonable skill and care in rendering their services.

A product seller may be deemed a “manufacturer” of the product (or component part of a product) in two situations. First, the product seller is a “manufacturer” of a product with respect to those aspects of a product (or component part of a product) which are created or affected when, before placing the product in the stream of commerce, the product seller produces, creates, makes, or constructs, and designs, or formulates, or has engaged another person to design or formulate, an aspect of a product (or component part of a product) made by another person.

For example, a company may manufacture a truck and deliver it to a product seller. Prior to selling that vehicle, the product seller may design and create what becomes a new aspect of the truck by, for example, adding a cabin unit. The product seller is, then, the manufacturer of the end product with respect to all aspects of the product that are affected or created by the addition (e.g., the cabin unit). Thus, the product seller is the “manufacturer” with respect to defects in the cabin unit itself and with respect to defects created by adding the unit to the original truck. This rule fairly holds

⁷⁶ See McCormick, *Handbook on the Law of Damages* 318 (1935).

⁷⁷ Title II of the Act also contains a definition for the term “harm.” See section 203(4). The definition found in section 203(4) is to be applied in actions governed by that Title.

⁷⁸ Where a court determines that a commercial loss resulting from damage caused by a product is recoverable in tort, in contravention of the traditional rule, those losses would be included in the definition of “harm” and the Act would apply.

⁷⁹ Title II of the Act also contains a definition for the term “manufacturer.” See section 203(6). The definition found in section 203(6) is to be applied in actions governed by that Title.

the product seller responsible for the consequences of designing and creating a new product from the original product; the Act does not intend to impose the manufacturer's liability on a product seller who merely cleans, paints, or reconditions the truck with parts that are designed or manufactured by someone else.

Second, a product seller is deemed to be the "manufacturer" of a product where the product seller holds itself out as the manufacturer to the user of the product. Where a product seller attaches the product seller's own private label to a product made by another, the product seller's name and reputation become a representation of the product's quality in design and manufacture. The rule holding a product seller responsible for harms caused by products that the product seller "endorses" with the product seller's private label is uniformly applied by the states.

(9) **NONECONOMIC LOSS.**—The term means subjective, nonmonetary loss resulting from harm, including pain, suffering, inconvenience, mental suffering, emotional distress, loss of society and companionship, loss of consortium, injury to reputation, and humiliation.

(10) **PERSON.**—The Act uses a broad definition of the term "person." The term is defined to include an individual, corporation, company, association, firm, partnership, society, joint stock company and any other entity (including governmental entities).

(11) **PRODUCT.**—The term is defined as any object, substance, mixture, or raw material in a gaseous, liquid, or solid state which, at the time of manufacture (i) is capable of delivery itself or as an assembled whole, in a mixed or combined state, or as a component part or ingredient; (ii) is produced for introduction into trade or commerce; (iii) has intrinsic economic value; and (iv) is intended for sale or lease to persons for commercial or personal use. The term does not include tissue, organs, blood, and blood products used for therapeutic or medical purposes, except to the extent that such tissue, organs, blood and blood products (or the provision thereof) are subject, under applicable State law, to a standard of liability other than negligence.⁸⁰ The term also does not include electricity, water delivered by a utility, natural gas, or steam.

(12) **PRODUCT LIABILITY ACTION.**—The term means a civil action brought on any theory for harm caused by a product.

(13) **PRODUCT SELLER.**—A "product seller" is any person who, in the course of a business conducted for that purpose, sells, distributes, rents, leases, prepares, blends, packages, labels, or otherwise is involved in placing a product in the stream of commerce, or who installs, repairs, refurbishes, reconditions, or maintains the harm-causing aspect of the product. The definition includes anyone in the chain of distribution, such as a wholesaler, distributor, or retailer.

⁸⁰ Claims for harm caused by tissue, organs, blood and blood products used for therapeutic or medical purposes are, in the view of most courts, claims for negligently performed services and are not subject to strict product liability. The Act thus respects State law by providing that, in those states, the law with respect to harms caused by these substances will not be changed. In the past, however, a few states have held that claims for these substances are subject to a standard of liability other than negligence, and this Act does not prevent them from doing so. See, e.g., *Cunningham v. MacNeal Memorial Hosp.*, 266 N.E.2d 897 (Ill. 1970) (overturned by Ill. Ann. Stat. Ch. 111¹, sections 2 and 3). Such actions, however, would be governed by the Act. The underlying principle is that if a state treats what is traditionally considered a service like a product by applying strict liability, then the action will be governed by the Act.

The term specifically excludes sellers or lessors of real property. Actions against such sellers or lessors will continue to be governed by state law.

The term also excludes providers of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services. Where, for example, an engineer, pharmacist, optician, or physician provides or uses a product in connection with that person's professional services, the person is not a product seller under the Act. The majority rule is that a professional is required to exercise reasonable care, prudence, and skill in rendering services. Where failure to do so results in harm, injured persons have remedies under traditional state tort law theories and do not have a claim under this Act.

If, however, a professional engages in a commercial transaction where the essence of the transaction is not the furnishing of professional skill and judgment, the professional may be a product seller. For example, a pharmacist who sells perfume or photographic film may be a product seller within the scope of the Act. In such a case, the sale rather than the exercise of professional skill is the essence of the transaction; the action would therefore be governed by the Act.

The term "product seller" also excludes persons who act in only a financial capacity with respect to the sale of a product or who lease a product under a lease arrangement in which the lessor does not select the leased product and does not during the lease term ordinarily control the daily operation and maintenance of the product. Such persons, called "finance lessors," generally have no contact with the product and do not provide advice about the product or its selection. These persons merely provide the money to transfer the product to the lessee. Courts that have considered the issue uniformly hold that finance lessors are not product sellers.

(14) PUNITIVE DAMAGES.—The term means damages awarded against any person or entity to punish or deter such person or entity, or others, from engaging in similar behavior in the future.

(15) STATE.—This definition is broad and is intended to include the District of Columbia, all the States, territories, and possessions of the United States, and any of their political subdivisions.

Section 102—Applicability; preemption

The U.S. Commerce Department reports that, on average, over seventy percent of the products that are manufactured in a particular state are shipped out of the state and sold.⁸¹ The current patchwork of varying state product liability laws sends confusing and often conflicting signals to those who use, make, or sell products in the United States. Uncertainties in our Nation's product liability system create unnecessary legal costs and impede interstate commerce and stifle innovation, among other problems. Scholars have recognized that the current product liability system does not distinguish well between good products and dangerous, defective prod-

⁸¹See Commodity Transportation Survey, U.S. Dept. of Commerce, Bureau of the Census, Table 1, pp. 1-7 (1977).

ucts. The Act helps make this distinction; it also simplifies the law, and reduces the costs and unpredictability of the current system.

Congress has the power under the Commerce Clause of the United States Constitution to enact a federal product liability statute that preempts state law.⁸² “Any such legislation would offend neither the Tenth Amendment’s recognition of state sovereignty . . . nor the Fifth Amendment’s traditional notions of due process and equal protection.”⁸³ Congress has long exercised its authority in matters of interstate commerce by enacting federal solutions to problems,⁸⁴ including the enactment of statutes that preempt state tort law.⁸⁵

For example, the 103rd Congress enacted the General Aviation Revitalization Act of 1994, which was signed by President Clinton on August 17, 1994.⁸⁶ That law established a uniform, national eighteen-year statute of repose for general aviation aircraft; it represents sound public policy and addressed a problem of interstate commerce. The 104th Congress enacted the Private Securities Litigation Reform Act of 1995,⁸⁷ the Federally Supported Health Centers Assistance Act of 1995,⁸⁸ and the Bill Emerson Good Samaritan Food Donation Act of 1996.⁸⁹ This Congress has already passed S. 543, the Volunteer Protection Act of 1997 and it will soon be sent to the President.

Federal product liability reform legislation is consistent with Congress’ traditional regulation of matters affecting interstate commerce. It is also consistent with the trend since the mid-1960s to-

⁸² See U.S. Const., art. I, § 8, cl. 3. The Commerce Clause power extends to interstate and intrastate activities which affect interstate commerce. See e.g., *Federal Energy Regulatory Comm’n v. Mississippi*, 456 U.S. 742 (1982); *Fry v. United States*, 421 U.S. 64842 (1976); *Katzbach v. McClung*, 379 U.S. 294 (1964); *Wickard v. Filburn*, 317 U.S. 111 (1942).

⁸³ Schmidt & Derman, *The Constitutionality of Federal Products Liability/Toxic Tort Legislation*, 6 J. Prod. Liab. 171, 184 (1983). See also *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 6489, 93 (1978) (Price-Anderson Act, which preempted state tort law in order to promote the nuclear power industry, is permissible under the Due Process and Equal Protection Clauses of the United States Constitution).

⁸⁴ For example, Congress enacted the United States Grain Standards Act in 1916, 7 U.S.C. §§ 71–87, 111, 113, 241–73, 2209 and 16 U.S.C. §§ 490, 683 (establishing uniform national standards for grain); the United States Cotton Standards Act in 1923, 7 U.S.C. §§ 51–65 (requiring uniform classifications for judging quality or value of cotton); the Tobacco Inspection Act in 1935, 7 U.S.C. §§ 511–511q (requiring compliance with uniform national classifications); the Public Utility Holding Company Act of 1935, 15 U.S.C. §§ 79 et seq. (activities involved “not susceptible of effective control by any State”); the Food, Drug and Cosmetic Act in 1938, 21 U.S.C. §§ 21 U.S.C. §§ 30192 (safety and labeling of drugs); the Consumer Product Safety Act in 1972, 15 U.S.C. §§ 2051–2083 and 5 U.S.C. §§ 5314, 5315 (uniform safety standards for consumer products); and the Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331 et seq. (national standards essential in order that “commerce and the national economy . . . not (be) impeded by diverse, nonuniform regulations”). The 104th Congress enacted the Aviation Disaster Family Assistance Act of 1996, Pub. L. No. 104–264, limiting unsolicited contacts by lawyers or insurance company representatives with airline crash victims or their families.

⁸⁵ See, e.g., Longshore and Harbor Workers’ Compensation Act, 33 U.S.C. §§ 901 et seq. (imposing liability without regard to fault); Price-Anderson Act, 42 U.S.C. § 2210 (limiting liability for nuclear power plant accidents); Federal Employers’ Liability Act, 45 U.S.C., §§ 51 et seq. (governing the liability of interstate railway carriers to their employees and altering State tort law on available defenses).

⁸⁶ Pub. L. No. 103–298, 108 Stat. 1552 (codified at 49 U.S.C. § 40101 note (West Supp. 1995)).

⁸⁷ Pub. L. No. 104–67, 109 Stat. 737 (placing limits on the conduct of private lawsuits under the Securities Act of 1933 and the Securities Exchange Act of 1934).

⁸⁸ Pub. L. No. 104–73, 109 Stat. 777 (extending Federal Tort Claims Act coverage to community, migrant, and homeless health centers).

⁸⁹ Pub. L. No. 104–210 (providing limited tort immunity to encourage the donation of food and grocery products to nonprofit organizations for distribution to needy individuals).

ward increased federal involvement in consumer product safety, an inherent part of interstate commerce.⁹⁰

Congress is also empowered by the Due Process Clause of the Fourteenth Amendment to the United States Constitution to implement federal punitive damages reform.⁹¹ The Fourteenth Amendment provides that no State shall “deprive any person of . . . liberty . . . without due process of law. . . .”⁹² As described later, the United States Supreme Court has expressly indicated in recent opinions that both substantive and procedural due process protections, as expressed in the Fourteenth Amendment, apply to punitive damages.

Furthermore, the Supremacy Clause of the United States Constitution gives Congress the power to enact a federal law that replaces state law in the area of product liability.⁹³ The fact that tort law is traditionally a matter of state law does not alter this rule, and it is expected that state and federal courts in product liability actions will interpret the Act in a manner consistent with the intent of Congress.

Despite the long history of Congressional involvement in matters affecting interstate commerce, some opponents of federal product liability reform have recently questioned whether Congress has the authority to enact product liability reform legislation in light of the United States Supreme Court’s 1995 decision in *United States v. Lopez*.⁹⁴

In *Lopez*, the Court addressed the Gun-Free School Zones Act of 1990, which made it a federal offense for any individual knowingly to possess a firearm at a place that individual knows or has reasonable cause to believe, is a school zone.⁹⁵ The Court determined that the Gun-Free School Zones Act exceeded Congress’ Commerce Clause authority, since possession of a gun in a local school zone was not economic activity that substantially affected interstate commerce.⁹⁶ The *Lopez* decision is completely distinguishable from those cases which directly support Congress’ Commerce Clause au-

⁹⁰ See, e.g., Consumer Product Safety Act, 15 U.S.C.A. §§ 2051 et seq. (1972); National Traffic and Motor Vehicle Safety Act, 15 U.S.C.A. §§ 1381 et seq. (1966); Magnuson-Moss Warranty—Federal Trade Commission Improvement Act, 15 U.S.C. §§ 2301–2312 (1982); Occupational Safety and Health (OSHA) Act, 29 U.S.C.A. §§ 651 et seq. (1970); Federal Hazardous Substances Act, 15 U.S.C.A. §§ 1261 et seq. (1960); Poison Prevention Packaging Act, 15 U.S.C.A. §§ 1471 et seq. (1970); Flammable Fabrics Act, 15 U.S.C.A. §§ 1191 et seq. (1972); Medical Device Amendments of 1976, 21 U.S.C. § 360c et seq. (1988 & Supp. 1993), to the Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 301 et seq. (1988 & Supp. 1993). See also Used Motor Vehicle Trade Regulation Rule, 16 C.F.R. § 455 (1995); Odometer Disclosure Requirement, 49 C.F.R. § 580 (1995); 21 C.F.R. § 101 et seq. (1995) (requiring uniform labeling of all packaged food products with ingredients and specific nutritional information). Ironically, professional consumer groups and others who advocate that product safety incentives provided by the tort system should be left to the states are also among the strongest proponents of federal regulation of matters affecting safety and health.

⁹¹ See generally William Volz and Michael Fayz, Punitive Damages And The Due Process Clause: The Search For Constitutional Standards, 69 U. Det. Mercy L. Rev. 459 (1992).

⁹² U.S. Const. amend XIV.

⁹³ See U.S. Const., art. VI, cl. 2. Under the Supremacy Clause, state courts are bound to apply federal law. See *Dice v. Akron, Canton & Youngstown R.R. Co.*, 342 U.S. 359 (1952) (Federal Employers’ Liability Act). In addition, when there is a variance between State and Federal law, “incompatible doctrines of local law must give ways to principles of federal . . . law.” *Local 174, Teamsters, Chauffeurs, Warehousemen and Helpers of Am. v. Lucas Flour Co.*, 369 U.S. 95, 102 (1962) (National Labor Relations Act).

⁹⁴ 111 S. Ct. 1624 (1995).

⁹⁵ See 18 U.S.C. § 922(q)(1)(A).

⁹⁶ *Lopez*, 111 S. Ct. at 1633. See also U.S. Const., Art. I, § 8, cl. 3. See generally Herbert Hovenkamp, Judicial Restraint And Constitutional Federalism: The Supreme Court’s *Lopez* And *Seminole Tribe* Decisions, 96 Colum. L. Rev. 2213 (1996).

thority over product liability.⁹⁷ In those cases, federal regulation is upheld when it involves activities that arise out of or are connected with commercial transactions, which viewed in the aggregate, substantially affect interstate commerce. Not only was the law at issue in *Lopez* “a criminal statute that by its terms has nothing to do with ‘commerce’ or any sort of economic enterprise,”⁹⁸ it also sought to regulate purely local activity (possession of a firearm within 1,000 feet of a school) that lacked any close “tie to interstate commerce.”⁹⁹ Product liability, in contrast, is without question a matter of interstate commerce and is, therefore, within the scope of Congress’ Commerce Clause authority.¹⁰⁰

Furthermore, the fact that some cases involving product liability appear to relate to intrastate activity does not undercut Congress’ Commerce Clause authority, because damages awards and legal costs associated with product liability create a hostile legal environment that discourages business activity. The United States Supreme Court’s opinion in *Hodel v. Virginia Surface Mining & Reclamation Association, Inc.*, 452 U.S. 264, 277 (1981), is instructive:

[T]his Court has made clear that the commerce power extends not only to “the use of interstate or foreign commerce” and to “protection of the instrumentalities of interstate commerce * * * or persons or things in commerce, but also to activities affecting commerce.” *Perez v. United States*, 402 U.S. 146, 150 (1971). As we explained in *Fry v. United States*, 421 U.S. 648, 547 (1975), “[e]ven activity that is purely intrastate in character may be regulated by Congress, when the activity, combined with like conduct by others similarly situated, affects commerce among the States or with foreign nations.

Section 102(a)(1) provides that the Act governs any product liability action brought in any State or Federal court on any theory for harm caused by a product.

Section 102(a)(2) provides that civil actions for commercial loss are not subject to the Act, but are governed by applicable commercial or contract law.

The Act follows the traditional rule applied in the overwhelming majority of states by indicating that claims for loss or damage caused to a product itself, loss relating to a dispute over the value of a product, or consequential economic loss (i.e., loss of profits due to an inability to use the damaged product) should be governed exclusively by applicable state commercial or contract law. The leading case is *Seeley v. White Motor Co.*, 403 P.2d 145 (Cal. 1965), which takes the position that damage to the product itself and com-

⁹⁷ See, e.g., *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1 (1937); *United States v. Darby*, 312 U.S. 100 (1941); *Wickard v. Filburn*, 317 U.S. 111 (1942).

⁹⁸ *Lopez*, 111 S. Ct. at 1630-31.

⁹⁹ *Id.* at 1633.

¹⁰⁰ Cf. *United States v. NL Indus., Inc.*, 936 F. Supp. 545 (S.D. Ill. 1996) (Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. § 9601 et seq., held to be a valid exercise of Congress’ Commerce Clause power). See generally Sherman Joyce, Product Liability Law In The Federal Arena, 19 Seattle U.L. Rev. 421, 427 (1996). In the area of punitive damages, the Due Process Clause of the Fourteenth Amendment to the United States Constitution provides an additional basis for Congress to enact reform legislation.

mercial losses are remedies that should be decided under the Uniform Commercial Code.¹⁰¹

The United States Supreme Court strongly endorsed this principle in an admiralty case, *East River Steamship Co. v. Transamerica Delaval, Inc.*, 476 U.S. 858 (1986). The American Law Institute's Restatement Of The Law Of Torts: Products Liability (Proposed Final Draft, April 1, 1997) states that product liability law applies only to "harm to persons or property"¹⁰² and also takes the position that "[w]hen a product defect results in harm to the product itself, the law governing commercial transactions" is the more appropriate source to resolve disputes between the parties, because such losses are, in essence, contract damages, not tort damages.¹⁰³

Section 102(b) provides that the Act supersedes State law only to the extent that State law applies to an issue covered under the Act. Any issue that is not covered under the Act, including any standard of liability applicable to a manufacturer, is not subject to the Act, but is subject to other applicable State or Federal law.

Section 102(c) lists a number of laws that are not superseded or affected by the Act. The Act does not waive or affect the defense of sovereign immunity of any State or of the United States; supersede or alter any Federal law;¹⁰⁴ waive or affect any defense of sovereign immunity asserted by the United States; affect the applicability of any provision of chapter 97 of title 28 of the United States Code; preempt state choice-of-law rules with respect to claims brought by a foreign nation or citizen of a foreign nation; or affect the right of any court to transfer venue or to apply the law of a foreign nation or to dismiss a claim of a foreign nation or of a citizen of a foreign nation on the ground of inconvenient forum.

The Act also does not supersede or modify any statutory or common law, including an action to abate a nuisance, that authorizes a person to institute an action for civil damages or civil penalties, cleanup costs, injunctions, restitution, cost recovery, punitive damages, or any other form of relief for remediation of the environment (as defined in section 101(8) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 U.S.C. 9601(8)).¹⁰⁵ Such actions, which are brought against owners or operators of facilities as opposed to product manufacturers, involve separate policy considerations and relate to acts that are different

¹⁰¹ In such cases where a court determines that commercial losses are recoverable under a tort theory, such losses are to be included within the definition of "harm" in this title and this Act would apply.

¹⁰² See The American Law Institute, Restatement of the Law of Torts: Products Liability (Proposed Final Draft, April 1, 1997), § 1.

¹⁰³ See id. § 21, comment d. The new Restatement (Third) was approved by the body of the American Law Institute on May 20, 1997. See also Note, Economic Loss in Product Liability Jurisprudence, 66 Colum. L. Rev. 927 (1966). It is the Committee's intent that where recovery is not allowed because of a state statute of limitations defense or other defenses to contract liability, the Act will not create an independent cause of action. For example, a claim could not be brought under the Act if recovery under state contract or commercial law is barred because of the statute of limitations, contractual disclaimers or limitations of remedies.

¹⁰⁴ For example, the provisions of the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b), 2671 et seq., the General Aviation Revitalization Act of 1994 (P.L. 103-298), the Oil Pollution Act of 1990 (P.L. 101-380), the Trans Alaska Pipeline Authorization Act (P.L. 93-153), and federal maritime law are not affected by the Act.

¹⁰⁵ The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 provides: "[E]nvironment" means (A) the navigable waters, the waters of the contiguous zone, and the ocean waters of which the natural resources are under the exclusive management authority of the United States under the Fishery Conservation and Management Act of 1976, and (B) any other surface water, ground water, drinking water supply, land surface or subsurface strata, or ambient air within the United States or under the jurisdiction of the United States."

from the acts for which this legislation provides rules of law. This provision makes clear that this Act does not apply to actions for damages resulting from releases into the environment, such as oil spills. The Act does apply to all product liability actions for harm, as defined in this title.

Section 102(d) makes it absolutely clear that civil actions for negligent entrustment or negligence in selling, leasing, or renting to an inappropriate party, are not subject to the Act, but are left to applicable State law. Specifically, the Act states: “A civil action for negligent entrustment, or any action brought under a theory of dramshop or third-party liability arising out of the sale or provision of alcohol products to intoxicated persons or minors, shall be subject to the provisions of this Act but shall be subject to any applicable State law.” This language has the support of Mothers Against Drunk Driving (MADD).

Thus, the Act would not cover a gun dealer that knowingly sells a gun to a convicted felon or a “straw man” fronting for children or felons, or a bar owner that knowingly serves a drink to an obviously inebriated person, or a car rental agency that rents a car to a person who is obviously unfit to drive. These actions would not be covered by the Act, because they involve a claim that the product seller was negligent or reckless in selling to the purchaser. The action is not based on a product defect. Negligent entrustment actions would continue to be governed by State law.¹⁰⁶

Section 103—Liability rules applicable to product sellers, renters, and lessors

Section 103 is intended to bring legal fairness to product sellers and reduce costs to consumers. Currently, under the law in about twenty-nine states, product sellers who wholesale, sell, rent or lease a product are potentially liable for defects that they are neither aware of nor able to discover. They are drawn into the overwhelming majority of product liability cases. Product sellers, however, rarely pay the judgment, because in virtually all of the cases where any liability is present, the manufacturer is held responsible for the harm. Based on this showing, the seller receives contribution or indemnity from the manufacturer, and the manufacturer ultimately pays the damages.

This approach generates substantial, unnecessary legal costs, which are passed on to consumers in the form of higher prices. A more efficient approach would be for the claimant to sue the product seller only if the product seller is directly at fault.

Section 103 “recognize[s] the unfairness and illogic of imposing ‘strict’ liability upon retailers and wholesalers who neither participate in the design process for products they sell, nor create warnings or instructions for a product.”¹⁰⁷ Following the lead of approximately twenty-one states,¹⁰⁸ Section 103 would hold prod-

¹⁰⁶For additional commentary explaining that the Act does not cover actions for negligent entrustment, see Cong. Record, March 21, 1996, S2575-76.

¹⁰⁷M. Stuart Madden, *The Vital Common Law: Its Role in a Statutory Age*, 18 U. Ark. Little Rock L.J. 555, 570 (1996).

¹⁰⁸See Colo. Rev. Stat. § 13-21-402 (1987); Del. Code Ann. tit. 18 § 7001 (1989); Ga. Code Ann. § 51-1-11.1 (Supp. 1995); Idaho Code § 6-1407 (1990); 735 ILCS 5/2-621 (1992) (formerly Ill. Rev. Stat. ch. 110, § 2-621 (1989)); Iowa Code § 613.18 (Supp. 1995); Kan. Stat. Ann. § 60-3306 (1994);

Continued

uct sellers, such as wholesalers and retailers, liable only if they are directly at fault for a harm (e.g. misassembled the product or failed to convey appropriate warnings to customers), unless the manufacturer of the product is out of business or otherwise not available to respond in a lawsuit. State “product seller” reform legislation has worked well; some state laws have existed for almost two decades and none have been repealed.

Section 103 assures that product sellers are not needlessly brought into product liability lawsuits. It also promotes sound public policy by encouraging product sellers to select the safest products for sale and to deal with responsible manufacturers who will be available and have assets in the United States in case a lawsuit arises because a product is defective. Finally, Section 103 assures that an injured consumer will always have available an avenue for recovery.¹⁰⁹

The Act also provides relief for companies, such as car and truck rental firms, that rent or lease products. These companies are subject in ten states and the District of Columbia to liability for the tortious acts of their lessees and renters, even if the rental company is not negligent and there is no defect in the product.¹¹⁰ In this minority of states, a rental company can be held vicariously liable for the negligence of its customers simply because the company owns the product and has given permission for its use. Vicarious liability—liability without regard to fault—increases costs for rental customers nationwide and imposes an undue burden on interstate commerce.

Section 103 specifies when a product seller other than a manufacturer is responsible for harm caused by a product. Section 103(a)(1) provides that a product seller is only liable for harm proximately caused (A) by its own failure to exercise reasonable care with respect to the product, (B) by a product that fails to conform to an express warranty made by the product seller, or (C) the product seller’s intentional wrongdoing. All three situations follow the rule that a product seller is responsible for the consequences of its own conduct.

Ky. Rev. Stat. Ann. § 411.340 (Michie/Bobbs-Merrill 1992); La. Rev. Stat. Ann. § 2800.53 (West 1991); Md. Cts. & Jud. Pro. Code Ann. § 5-311 (1982); Mich. Comp. Laws § 600.2947(6) (1996); Minn. Stat. § 544.41 (West 1988); Mo. Rev. Stat. § 537.762 (1988); Neb. Rev. Stat. § 25-21,181 (1995); N.C. Gen. Stat. § 99B-2 (1995); N.D. Cent. Code § 28-01.3-04 (Supp. 1995); N.J. Stat. Ann. § 2A:58C-9 (1995); Ohio Rev. Code Ann. § 2307.78 (Anderson 1991); S.D. Codified Laws § 20-9-9 (1995); Tenn. Code Ann. § 29-28-106 (Supp. 1995); Wash. Rev. Code § 7.72.040 (West 1992).

¹⁰⁹Two reasons have been advanced for holding product sellers liable as if they were manufacturers. First, it has been argued that the rule promotes safety and reduces the risk of harm, because product sellers will seek to avoid liability by pressuring manufacturers to make safe products. See, e.g., *Vandermark v. Ford Motor Co.*, 391 P.2d 168 (1964). This rationale, however, fails to recognize that manufacturers will feel the same, if not greater, pressure to make safe products if they are sued directly for harms caused by their own product defects. Second, it has been argued that the rule is fair because a product seller who is held liable for harm caused by a manufacturer’s defect can seek indemnity, see, e.g., Ark. Stat. Ann. § 16-116-107, and thereby shift the cost of liability to the manufacturer who actually caused the harm. See, e.g., *Hales v. Monroe*, 544 F.2d 331 (8th Cir. 1976); *Litton Systems Inc. v. Shaw’s Sales & Serv., Ltd.*, 579 P.2d 48 (Ariz. App. 1978). Data show that, in fact, product sellers account for less than five percent of product liability payments, because generally they are either dismissed or indemnified.

¹¹⁰See Cal. Veh. Code § 17150-51 (West 1971); Conn. Gen. Stat. Ann. § 14-154a (West 1987); D.C. Code Ann. § 40-408 (1990); Fla. Stat. Ann. § 324.021(9)(b) (Supp. 1994) (exempts leased vehicles); Idaho Code § 49-2417 (1994); Iowa Code § 321.493 (1985); Me. Rev. Stat. Ann. 29-A § 1652-53 (Supp. 1995); Mich. Comp. Laws Ann. § 257.401 (West Supp. 1995); Minn. Stat. § 170.54 (1986); N.Y. Veh. & Traf. § 388 (McKinney 1986); R.I. Gen. Laws § 31-33-6, 31-33-7 (1995).

Section 103(a)(2) provides that, except for breach of express warranty, a product seller will not be liable if there was no reasonable opportunity to inspect the product, or if the inspection, in the exercise of reasonable care, would not have revealed the aspect of the product which allegedly caused the claimant's harm. For example, a seller may not have had a reasonable opportunity to discover a product defect if the product was prepackaged or if the product never passed through the seller's hands (e.g., a person may have held title to the product, but never had possession of the product).

Section 103(b)(1) provides that a product seller shall be treated as the product manufacturer and shall be liable for the claimant's harm as if the product seller were the manufacturer if (A) the manufacturer is not subject to service of process under the laws of any state in which the action might have been brought by the claimant, or (B) the court determines that the claimant would be unable to enforce a judgment against the manufacturer. For example, a judgment would be unenforceable if the court finds that the manufacturer is bankrupt, insolvent, or otherwise unable to pay. A claimant may recover from the product seller for harms that were caused by the manufacturer if one of the two provisions applies, and if the claimant proves that the manufacturer would have been liable under state law.

To prevent the situation where a claimant may not become aware until after the statute of limitations has expired that the manufacturer lacks funds sufficient to satisfy the judgment, section 103(b)(2) provides that, for purposes of this subsection only, the statute of limitations applicable to claims asserting liability of a product seller as a manufacturer shall be tolled from the date of the filing of a complaint against the manufacturer to the date that judgment is entered against the manufacturer. Although section 103(b) departs from the notion of individual responsibility for harms, it ensures that a claimant can recover from the product seller if he or she is unable to recover from the manufacturer responsible for the harm.

Section 103(c)(1) provides that parties engaged in the business of renting or leasing products, other than a person excluded from the definition of "product seller" under section 101(13)(B), shall be subject to liability in a product liability action in a manner similar to product sellers under section 103(a).

Section 103(c)(1) also preempts state vicarious liability laws, which hold the owner of a product, such as a motor vehicle, liable for the negligence of a user of the product, regardless of whether the owner of the product was negligent.¹¹¹ The Act provides that any person engaged in the business of renting or leasing a product, including finance lessors, shall not be liable to a claimant for the tortious act of another solely by reason of ownership of the product.

Section 103(c)(2) provides that, for purposes of section 103(c)(1) and for determining the applicability of this title to any person subject to section 103(c)(1), the term "product liability action" means

¹¹¹The Committee does not intend that section 103(c) preempt state minimum financial responsibility laws for motor vehicles. This subsection does not relieve the owner of any motor vehicle of responsibility to insure the vehicle to the amounts required under appropriate state law.

a civil action brought on any theory for harm caused by a product or product use.

Section 104—Defenses based on claimant's use of alcohol or drugs

In about eleven states, a person who is inebriated or under the influence of illegal drugs can recover in a product liability action, even though that illegal condition was a substantial cause of the harm.¹¹² The Act will put an end to that situation if the defendant proves that the plaintiff was under the influence of intoxicating alcohol or any drug when the accident or other event which resulted in such claimant's harm occurred, and the defendant shows that such condition was the cause of the accident or other event. The provision is based on a statute in the State of Washington.¹¹³

This defense implements sound public policy. It tells persons that if they abuse alcohol or drugs they will not be rewarded through the product liability system. This rule will encourage persons to take responsibility for their own safety. It also relieves ordinary consumers from the burden of paying more for products to subsidize the illegal or imprudent conduct of others. It will discourage drunk driving, a major cause of death on our nation's highways.

Section 104(a) establishes a complete defense for any defendant in a product liability action if the defendant can prove that the claimant was under the influence of intoxicating alcohol or any drug when the accident or other event which resulted in such claimant's harm occurred, and the claimant, as a result of such condition, was more than fifty percent responsible for such accident or other event.¹¹⁴

Section 104(b)(1) provides that the determination of whether a person was intoxicated or was under the influence of intoxicating alcohol or drugs shall be made pursuant to applicable state law. For example, if applicable state law provides that a particular amount of alcohol in a person's blood is evidence that the person was under the influence of intoxicating alcohol, that standard shall apply.

Section 104(b)(2) provides that the term "drug" means any controlled substance as defined in the Controlled Substances Act (21 U.S.C. 802(6)) that was not legally prescribed for use by the claimant or that was taken by the claimant other than in accordance with the terms of a lawfully issued prescription.

¹¹²The majority of states have laws which do not permit recovery in this situation. Four states, Alabama, Maryland, North Carolina, and Virginia, and the District of Columbia, continue to recognize contributory negligence as an absolute defense. Thirty-two states have adopted some form of modified comparative fault standard: Arkansas, Delaware, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Texas, Tennessee, Utah, Vermont, West Virginia, Wisconsin and Wyoming.

¹¹³See Wash. Rev. Code Ann. § 5.40.060 (West 1996).

¹¹⁴This provision only addresses situations in which, currently, a person could bring a successful claim when such person was more than fifty percent responsible for their own harm due to abuse of drugs or alcohol. If a state has pure comparative fault as its general rule of tort law, this provision will prevail if the claimant was under the influence of alcohol or any drug and such condition was more than fifty percent responsible for the harm. The Act is not preemptive if a state retains the contributory negligence defense and believes that a person's claim should be barred if the person's fault in any way contributed to his or her harm.

Section 105—Reduction for misuse or alteration of product

This section addresses the situation where a product has been used in a manner unintended by the manufacturer either through misuse or alteration of the product. When a product is misused or altered, this section allows for the reduction of damages when liability or recovery of damages otherwise exists under Federal or State law. This provision avoids placing the cost of that misuse or alteration on the manufacturer and, ultimately, onto ordinary, responsible consumers. The section places emphasis on basic fairness and individual responsibility. This common sense provision is supported by two strong rationales: (1) liability law should be based upon individual responsibility and should encourage the safe use of products, and (2) consumers should not be forced to pay more for products due to others' misuse or alteration of products.

Section 105(a)(1) provides that, in a product liability action, the damages for which a defendant is otherwise liable under Federal or State law shall be reduced by the percentage of responsibility for the harm to the claimant attributable to misuse or alteration of a product by any person. The defendant must establish that this percentage of the harm was proximately caused by a use or alteration of a product either (A) in violation of, or contrary to, the express warnings or instructions of the defendant, if the warnings or instructions are determined to be adequate pursuant to applicable State law, or (B) involved a risk of harm relating to misuse or alteration which was known or should have been known by the ordinary person who uses or consumes the product with the knowledge common to the class of persons who used or would be reasonably anticipated to use the product.

The phrase "otherwise liable under Federal or State law" makes clear that this section does not create liability under State law that does not otherwise exist. Nor does this section provide for the award of damages that presently are barred by State law. Rather, this section allows for the reduction of damages based upon the misuse or alteration of a product by an individual where liability otherwise exists and/or where recovery is not otherwise barred. When the defendant is "otherwise liable under Federal or State law", the operation of this section holds an individual accountable for any harm resulting from the misuse or alteration of a product and apportions damages between or among the parties resulting from this misuse or alteration where existing State law does not already impose such apportioning of damages.

For example, if under State law, the defendant has no liability under the "common knowledge" doctrine, then this section would not change that result.¹¹⁵ Under the "common knowledge" doctrine, the defendant is not held responsible to the plaintiff for injury caused by the plaintiff's misuse of a product that is commonly known by ordinary consumers to be dangerous. Since in this example, section 105 does not change the existing State law which determines liability—the common knowledge doctrine—State law is not preempted by the Act.

¹¹⁵ See Cong. Record, May 9, 1995, at S6329-30. See also *Friar v. Caterpillar, Inc.*, 529 So. 2d 509 (La. App. 1988); *Colson v. Allied Products Corp.*, 640 F.2d. 5 (5th Cir. 1981); Restatement (Second) of Torts § 402A cmts. i and j (1965).

Two other instances where this section does not effect State law are noteworthy. If a State has the contributory negligence defense which bars a person from recovering any damages if that person's fault in any way contributed to his or her harm, then State law will continue to apply to those product liability actions without interruption by this section. The same result occurs if a State has adopted a "modified" form of comparative fault which bars a person from recovering any damages depending upon the percentage of fault for the harm attributed to that person, and that percentage of fault is met.

Section 105(a)(2) states that a use of a product that is intended by the manufacturer of the product does not constitute a misuse or alteration of the product.

Section 105(b) provides that, notwithstanding subsection (a), the amount of damages for which a defendant is otherwise liable under State law shall not be reduced by the application of section 105 with respect to the conduct of any employer or coemployee of the plaintiff who is, under applicable State law concerning workplace injuries, immune from being subject to an action by the claimant.

Section 106—Uniform time limitations on liability

All civil actions governed by the Act are subject to a nationally uniform "discovery rule" statute of limitations. A discovery rule favors plaintiffs because the statute of limitations only begins to run once the claimant discovers, or in the exercise of reasonable care should have discovered, both the harm that is the subject of the action and the cause of the harm. The Act also establishes a nationally uniform statute of repose of 18 years for product liability actions. The statute of repose establishes the time period during which a manufacturer or product seller may be held responsible for harm allegedly caused by a product. The statute of repose does not apply to cases involving a "toxic harm" (i.e., a latent physical injury).

STATUTE OF LIMITATIONS

All states have statutes of limitations that apply to product liability actions.¹¹⁶ A statute of limitations specifies that time, following some triggering event, within which the claimant must file his or her action. Failure to file within the specified time bars the claim.

In some states, such as Virginia, the starting point for a person to bring a claim begins to run at the "time of injury."¹¹⁷ When an injury caused by a product is immediate and traumatic, this date is easy to determine. The claimant generally knows of his or her harm and the cause of the harm at the time of the injury. Where the harm is latent, however, the claimant may not know that he

¹¹⁶ Under present law, different statutes of limitations apply in product liability actions depending upon the particular theory of the case. For example, a statute of limitations applicable in tort may be the rule in an action based on negligence, while a statute of limitations applicable in contract may be the rule in an action based on breach of warranty. The Act will establish one uniform, national statute of limitations for all product liability actions. Moreover, the Act will provide a uniform rule, vastly improving the current patchwork state system to the benefit of all who use, sell, and make products in the United States.

¹¹⁷ See, e.g., *Hawks v. DeHart*, 146 S.E.2d 187 (Va. 1966). See also *Wojcik v. Almase*, 451 N.E.2d 336 (Ind. App. 1983); *New Mexico Elec. Serv. Co. v. Montanez*, 551 P.2d 634 (N.M. 1976).

or she has been harmed or the cause of that harm. In these situations, a “time of injury” statute of limitations may expire and bar a claim before the claimant is even aware of the injury and a potential claim.

In response to this problem, some states have adopted a rule under which the limitations period begins to run when the claimant discovers the harm.¹¹⁸ Even this rule may be unfair, however, because the claimant may not discover the actual cause of the harm until some time after the harm is discovered. The statute of limitations may expire before the claimant can reasonably discover both the harm and its cause.¹¹⁹

In contrast, the Act provides that the two-year period within which a plaintiff may bring a product liability action starts on the date that the claimant, or if the claimant has died the person entitled to bring the claim, knows, or in the exercise of reasonable care should know, both that a harm has occurred and the cause of that harm. Thus, the Act will reduce the number of plaintiffs who, having otherwise meritorious claims, would be denied justice solely on the basis of their choice of the state in which they choose to file a claim.

The Act will also alleviate the potential hardship caused by the statutes of limitations periods contained in state wrongful death statutes. Most of these statutes bar claims a certain number of years after a death. The Act would preserve these claims for the “discovery” period, i.e., until two years after a surviving relative discovered or in the exercise of reasonable care should have discovered, the cause of his or her loved one’s death. This rule would modify existing state law in a positive way for claimants.

Section 106(a)(1) provides that, in any civil action brought under the Act, the complaint must be filed within two years of the date the claimant discovers or, in the exercise of reasonable care, should have discovered, (A) the harm that is the subject of the action, and (B) the cause of the harm. Product liability actions are barred if filed after this time period.

Section 106(a)(2) provides that if a person with a product liability claim has a legal disability as determined under applicable law (e.g., the person is a minor or is insane), the person may file a product liability action not later than two years after the date on which the legal disability ceases.

Section 106(a)(3) provides that if the commencement of a product liability action is stayed or enjoined, the running of the statute of limitations shall be suspended until the end of the period that the stay or injunction is in effect.

This section must be read in light of section 303 to accurately determine its applicability. This section is applicable to harms that are discovered or, in exercise of reasonable care, should have been discovered after the date of enactment of this law although the

¹¹⁸ See, e.g., Conn. Gen. Stat. 52-577(a) (1983); *Witherall v. Weimer*, 421 N.E.2d 869 (Ill. 1981); *Hansen v. A.H. Robins, Inc.*, 335 N.W.2d 578 (Wis. 1983).

¹¹⁹ See *Koepnick v. Aequitron Medical, Inc.*, No. 921-1975 (6th Cir. Aug. 3, 1993). As one judge said, this follows the logic of “topsy-turvy land” where one can “be divorced before [he] ever . . . mar[r]ies], or harvest a crop never planted, or burn down a house never built, or miss a train running on a non-existent railroad.” *Dincher v. Marlin Firearms Co.*, 198 F.2d 821, 823 (2d Cir. 1952) (Frank J., dissenting).

harm that is the subject of the action or the conduct that caused the harm may have occurred before such date of enactment.

STATUTE OF REPOSE

For over a decade and a half, numerous small business owners have testified about the effect of liability for old products. The products have been used safely for a substantial period of time and manufacturers are willing to stand behind warranties they made about how long a product will last. Nevertheless, as a result of “long tail” liability, some of these companies are, by no fault of their own, falling behind competitively, because they are disadvantaged by liability rules that create an artificial preference for newer, mostly foreign, industries.

For example, Charles E. Gilbert, Jr., President of Cincinnati Gilbert Machine Tool Company, testified before the House Judiciary Committee in February 1995 that his company is subject to liability for machine tools manufactured over 100 years ago. He noted these older products usually pass through several owners, each making adjustments and changes to suit their own needs, until eventually the product causes harm, through no fault of the manufacturer, and a lawsuit ensues. Cincinnati Gilbert, like most manufacturers, almost always wins these lawsuits concerning older products, yet it must invest time and resources into legal costs. Excess legal costs sap international competitiveness, retard job growth, and limit research and development.

Principal competitors of the United States have enacted legislation recognizing that, at some point, an outer time limit on litigation is reasonable and necessary. The new Japanese product liability law and the European Community Product Liability Directive (which has also been adopted by Australia) each have a ten-year statute of repose which covers all products.

Statutes of repose reflect the public policy that, after the passage of a reasonable length of time, manufacturers should be free from the burdens of disruptive litigation over products that are alleged to cause harm after many years of safe operation and use.

In the United States, approximately 19 states have enacted product liability statutes of repose, ranging from six years to a maximum of fifteen years; the typical repose period is between ten and twelve years.¹²⁰

¹²⁰ Statutes of repose exist in the following states: Ark. Code Ann. § 16-116-1059(c) (Michie 1987) (use of a product beyond its “anticipated life” may be considered as evidence of fault by the consumer); Colo. Rev. Stat. § 13-21-403 (1987) (rebuttable presumption that the product is not defective after 10 years); Colo. Rev. Stat. § 13-80-107 (1987) (7 years for new manufacturing equipment); Conn. Gen. Stat. § 52-577a (1991 & Supp. 1995) (10 years); Ga. Code Ann. § 51-1-11(b)(2) (1982 & Supp. 1995) (10 years); Idaho Code § 6-1403(2) (1990) (“useful safe life” of product, rebuttable presumption of 10 years); Ill. Ann. Stat. § 735, 5/13-213(b) (Smith-Hurd 1992) (12 years from date of first sale, or 10 years from date of sale to first user, whichever is shorter); Ind. Code Ann. § 33-1-1.5-5(b) Burns 1992) (10 years); Iowa H.B. 693 (signed by Governor on May 29, 1997) (15 years); Kan. Stat. Ann. § 60-3303 (1994) (“useful safe life” of product, rebuttable presumption of 10 years); Ky. Rev. Stat. Ann. § 411.310(1) (Michie/Bobbs-Merrill 1992) (rebuttable presumption that product is not defective if harm occurred five years after sale to first consumer or eight years after manufacture); Mich. Stat. Ann. § 27A.5805 (Callaghan 1986 & Supp. 1995) (if product in use for 10 years, plaintiff must prove prima facie case without benefit of any presumption); Minn. Stat. Ann. § 604.03 (West 1988) (“useful life” of product); Neb. Rev. Stat. § 25-224 (1995) (10 years); N.D. Cent. Code § 28-01.3-08(1) (Supp. 1995) (10 years); Or. Rev. Stat. § 30.905(1) (1995) (8 years); Tenn. Code Ann. § 29-28-103(a) (1988 & Supp. 1995) (10 years); Tex. Civ. Prac. & Rem. Code Ann. § 16.012 (West Supp. 1995) (15 years for non-agricultural manufacturing equipment); Wash. Rev. Code § 7.72.060(1) (West 1992) (“useful safe life”

At the federal level, on August 17, 1994, President Clinton signed the General Aviation Revitalization Act of 1994 (GARA), which created a uniform, federal eighteen-year statute of repose for general aviation aircraft.¹²¹ President Clinton has pointed with pride to his support for GARA. In a presidential debate held on October 6, 1996, President Clinton said: "I signed a tort reform bill that dealt with civil aviation a couple of years ago. I proved that I will sign reasonable tort reform."

On Thursday, March 6, 1997, the Consumer Affairs Subcommittee held a hearing to explore the positive effects resulting from GARA. The hearing established that GARA has worked very well.¹²² GARA is a sound model for a broad federal product liability statute of repose.

John Moore, Senior Vice President of Human Resources for Cessna Aircraft Company, testified that Cessna withdrew from the single engine aircraft in 1986. At that time, \$80,000 of every aircraft manufactured by Cessna went to pay product liability costs. Prior to the enactment of GARA, Cessna CEO Russ Meyer promised that if Congress enacted product liability legislation to protect the general aviation industry, Cessna would resume manufacturing small aircraft. True to his word, Cessna is back in the single engine aircraft business. It has invested \$55 million in facilities and equipment. Presently, its small aircraft division has over 650 employees, with plans to double employment in 1998. Cessna expects \$100 million in sales in 1997 and projects \$350 to 400 million in sales by the year 2000.

John S. Yodice, General Counsel of the Aircraft Owners and Pilots Association, an association that represents 340,000 aviators, testified that, prior to GARA, his members realized that they were paying higher costs for aircraft, because of product liability costs. Therefore, they supported GARA. He reported that GARA has created a renewed spirit among members of the general aviation community. Significantly, his group has not heard of any complaints from consumers about GARA.

Paul Newman, Chief Financial Officer of the New Piper Aircraft Corporation, testified that GARA permitted New Piper to emerge from a Chapter 11 bankruptcy that had idled 1,000 workers. As a direct result of GARA, Piper has emerged from bankruptcy liquidation and is now producing planes and has 650 employees.

Bradley Mottier, Senior Vice President of Unison Industries of Jacksonville, Florida, a supplier of aircraft ignition systems, said the GARA has encouraged the company to market components that improve pilot safety. Before GARA, because of product liability concerns, Unison held back from introducing a state of the art digital ignition system which it had developed in 1986. With the passage of GARA, the safer digital ignition system is now available to pilots and their passengers. Next year, Unison Industries plans to introduce a laser operated starting system.

of product, rebuttable presumption of 12 years); Ohio Rev. Code Ann. §§ 2125.02(D)(2) and 2305.10(c)(Banks-Baldwin 1997) (15 years).

¹²¹ See General Aircraft Revitalization Act of 1994, Pub. L. No. 103-298, 108 Stat. 1552 (codified at 49 U.S.C. § 40101 note (West Supp. 1995)).

¹²² See generally Geoffrey A. Campbell, Study: Business Booms After Tort Reform Enacted, ABA J., at 28 (Jan. 1996) ("The light aircraft industry is taking off as reduced liability encourages technological innovation.")

The Subcommittee also heard from John Peterson of the Montgomery County Action Council of Coffeyville, Kansas, who testified about the positive “ripple effects” of GARA on communities. Cessna’s new small aircraft plant is located in his county. Mr. Peterson said that, prior to 1995, Montgomery County ranked ninety-eighth out of 105 Kansas counties in economic indicators. Its population was dropping, employment was on the decline, per capita income was down, and property values were depressed. Economic growth since the construction of the plant began has exceeded all predictions made in a study the county prepared in 1995. New housing starts are up 260 percent, the value of new homes has doubled, retail sales are up five percent, per capita income has nearly doubled, and nearly 500 people per year are moving into the county.

Consistent with GARA, the Act provides a uniform national 18-year statute of repose for product liability actions. This period of time is longer than any of the existing state statutes of repose that establish a fixed period of time.¹²³ This provision, therefore, expands the period of time in which plaintiffs can bring actions in many states. For example, it more than doubles the period in which a plaintiff in Oregon (which has an 8-year statute of repose) can bring an action; it increases by 80% the period of time in which a plaintiff in North Dakota (which has a 10-year statute of repose) can bring an action.

The statute of repose excepts products alleged to cause “toxic harm.” Some expressed concern about products that may cause physical injuries that do not manifest themselves for many years after a person is first exposed to a product. The exception for toxic harm, therefore, is intended to address the unfairness that could result if an individual were injured by a product during the repose period, but the harm did not manifest itself until after that period.

The statute of repose does not immediately bar claimants or potential claimants with existing causes of action from bringing lawsuits, regardless of when the products on which the suits may be based were sold. The Act contains a transitional provision that extends for one year the period for bringing actions that would otherwise be barred. Thus, for example, if the statute of repose would shorten the period of time during which a product liability action could be otherwise brought under State law, an individual injured by a product manufactured 50 or even 100 years ago would have an additional year after the date of enactment of the Act to bring an action.

Section 106(b)(1) provides that any product liability action alleging harm, which is not toxic harm, caused by any product is barred unless the complaint is served and filed within eighteen years of the time of delivery of the product to its first purchaser or lessee.

Section 106(b)(2)(A) excludes motor vehicles, vessels, aircraft, and trains from the statute of repose provision where such products are used primarily to transport passengers for hire. Otherwise, these products are subject to the rule set forth in section 106(b)(1).

¹²³ Some state statutes of repose are tied to “useful safe life” or provide rebuttable presumptions, rather than fixed periods of repose.

Section 106(b)(2)(B) extends the repose period in situations where a defendant has made an express warranty in writing as to the safety of its product. If the warranty extends beyond the 18-year time limitation in the Act, the repose limitation goes into effect at the expiration of that warranty.

TRANSITIONAL PROVISION

Section 106(c) provides that if any provision of sections 106(a) or 106(b) of the Act would shorten the period during which a product liability action could otherwise be brought pursuant to another provision of law, the claimant may, notwithstanding sections 106(a) or 106(b), bring an action within one year after the effective date of the Act. This exception is intended to prevent unfair situations from arising as a result of the application of the time limitations set forth in the Act.

Section 107—Alternative dispute resolution procedures

The legal system is inaccessible to many product liability claimants, because of its complexity and expense. The Act establishes a scheme for expedited settlement of product liability claims in the initial stages of litigation. The provision on alternative dispute resolution (ADR) procedures could reduce the delays, excessive transaction costs, and uncertainties associated with product liability claims. It will also encourage more speedy resolution of product liability disputes so that compensation reaches injured persons more quickly.

The Act allows either party to a product liability dispute to offer to proceed pursuant to any voluntary and nonbinding ADR procedures established in the state where the action is brought or under the rules of the court in which the action is maintained.¹²⁴ The Act requires the offer to proceed to ADR to be made within 60 days after service of the initial complaint or the applicable deadline for a responsive pleading, whichever is later. There is no penalty on a party who refuses to proceed to ADR.

The ADR provision will be especially beneficial for persons with smaller claims, because these persons are frequently unable to obtain lawyers to represent them in expensive courtroom litigation. Such plaintiffs, however, can more easily secure attorneys to represent them in ADR proceedings, which are free of cumbersome rules of procedure and evidence and do not require the use of expensive expert witnesses. Moreover, many plaintiffs desire to and are capable of representing themselves in ADR proceedings.

William Fry, Executive Director of HALT, a nonprofit legal reform organization supported by 70,000 individual members nationwide, testified at an April 3, 1995, Subcommittee hearing that ADR mechanisms are “a way to lower costs, simplify procedures and achieve fairness through avoidance of technical rules of law.”¹²⁵ HALT supports the use of alternative dispute resolution mechanisms to permit consumers to handle their own legal affairs.

¹²⁴“The ABA strongly supports voluntary ADR.” American Bar Association, *An Agenda for Justice: ABA Perspectives on Criminal and Civil Justice Issues* 88 (July 1996). Nonbinding ADR procedures do not violate the right to jury trial found in the Seventh Amendment. See *Kimbrough v. Holiday Inn*, 478 F. Supp. 566 (E.D. Pa. 1979).

¹²⁵S. Hrg. 104-435 at 86.

Section 107 also meets the spirit of President Clinton's February 5, 1996, Executive Order 12988, which encouraged counsel participating in civil litigation on behalf of the United States Government to make "broader and effective use of informal and formal ADR methods."

Section 107(a) provides that either a claimant or a defendant may offer to proceed pursuant to a voluntary and nonbinding ADR procedure established in the state where the action is brought or under the rules of the court in which the action is maintained. The offer to proceed to ADR must be made within sixty days after service of the initial complaint or the applicable deadline for a responsive pleading, whichever is later.

Section 107(b) provides that not later than ten days after the service of an offer to proceed under an ADR procedure the offeree shall file a written notice accepting or rejecting the offer.

Section 107(c) provides that the court may, upon motion by an offeree made prior to the expiration of the ten-day period specified in section 107(b), extend the period for filing a written notice under that subsection for a period of not more than sixty days after the date of expiration of the period specified in section 107(b). Discovery may be permitted during this period.

Section 108—Uniform standards for award of punitive damages

The United States Supreme Court has observed that punitive damages have "run wild" in the United States, jeopardizing fundamental constitutional rights.¹²⁶ The Court has held that the Due Process Clause of the Fourteenth Amendment imposes a substantive limit on the size of punitive damages awards.¹²⁷ It has also held that the Constitution provides procedural limits on when and how punitive damages may be awarded.¹²⁸

DUTY OF CONGRESS TO PROTECT DUE PROCESS RIGHTS

Congress and the Supreme Court share responsibility for guarding due process rights. This principle is expressly reflected in both the "Findings" and "Purposes" of the Act.¹²⁹ Some Justices have made the practical observation that the Supreme Court cannot fashion highly specific rules in the area of punitive damages, and therefore have "invited" remedial legislation.¹³⁰ It is the duty of

¹²⁶ *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 18 (1991).

¹²⁷ See *BMW of N. America, Inc. v. Gore*, 116 S. Ct. 1589, 1604 (1996). See also *TXO Prod. Corp. v. Alliance Resources Corp.*, 509 U.S. 443, 458 (1993); *Pacific Mutual Life Ins. Co.*, 499 U.S. at 23–24; *Honda Motor Corp., Ltd. v. Oberg*, 114 S. Ct. 2331, 2340 (1994). Cf. *Pulla v. Amoco Oil Co.*, 72 F.3d 648, 661 (8th Cir. 1995) (opinion by retired Supreme Court Justice Byron White) (striking down punitive damages award as "excessive, unreasonable and violative of due process").

¹²⁸ In *Honda Motor Corp.*, 114 S. Ct. at 2340, a case involving an all terrain vehicle that flipped over when an inebriated plaintiff tried to drive it up a hill, the Court struck down a punitive damages award on the ground that Oregon law violated due process, because it did not provide an opportunity for meaningful appellate review of the size of punitive damages awards.

¹²⁹ See Section 2(a)(9) ("[I]t is the constitutional role of the national government to remove barriers to interstate commerce and to protect due process rights"); section 2(b) (stating that a purpose of the Act is "to uphold constitutionally protected due process rights" of punitive damages defendants).

¹³⁰ See *TXO Prod. Corp.*, 509 U.S. at 2727 (Scalia and Thomas, J.J., concurring in the judgment). See also Richard Neely, Needed: Legal Standards on Punitive Damages, *The Wall St. J.*, Wed., July 14, 1993, at A13 (expressing belief that the Supreme Court's "refusal" to set clear standards for awarding punitive damages in civil cases is "a disappointment to those of us who believe that large punitive damages awards are retarding research, development, product introduction and job creation." Justice Neely delivered the opinion in the *TXO* case when it was con-

Congress to respond to the Court's concern about punitive damages that are "run wild" by enacting meaningful reforms that will safeguard constitutionally protected due process rights and remove substantial barriers to interstate commerce.

BOTH THE DUE PROCESS CLAUSE OF FOURTEENTH AMENDMENT AND
THE COMMERCE CLAUSE OF THE UNITED STATES CONSTITUTION EM-
POWER CONGRESS TO ACT

Congress is empowered by the Due Process Clause of the Fourteenth Amendment to the United States Constitution to implement federal punitive damages reforms.¹³¹ The Fourteenth Amendment provides that no State shall "deprive any person of . . . liberty . . . without due process of law. . . ."¹³² As indicated above, the Supreme Court has expressly indicated that substantive and procedural due process protections, as expressed in the Fourteenth Amendment, apply to punitive damages cases.

Furthermore, Section Five of the Fourteenth Amendment provides that "Congress shall have power to enforce, by appropriate legislation, the provisions of th[at] article."¹³³ The Supreme Court has interpreted this language as a conveyance of a very broad power, giving Congress "the same broad powers expressed in the necessary and proper clause."¹³⁴ Unless prohibited by some other provision of the Constitution, it is within the power of Congress to enact "[w]hatever legislation is appropriate, that is, adapted to carry out the objects the Amendments have in view."¹³⁵ Federal legislation to reform punitive damages falls squarely within the "broad power" of Congress to implement rules which "carry out" both the letter and spirit of the Fourteenth Amendment.

Congress also has the power under the Commerce Clause of the United States Constitution to enact federal reform legislation concerning punitive damages. Article I, Section Eight of the Constitution provides that Congress shall have the power "To regulate Commerce . . . among the several States. . . ."¹³⁶ This power extends to interstate and intrastate activities that affect interstate commerce.¹³⁷ Punitive damages awards affect interstate commerce and, unquestionably, fall within the scope of activities that can be regulated by Congress.

sidered before the West Virginia Supreme Court on its way to the United States Supreme Court).

¹³¹ See generally William Volz and Michael Fayz, *Punitive Damages And The Due Process Clause: The Search For Constitutional Standards*, 69 U. Det. Mercy L. Rev. 459 (1992).

¹³² U.S. Const. amend XIV.

¹³³ U.S. Const. amend XIV, § 5.

¹³⁴ *Katzenbach v. Morgan*, 384 U.S. 641, 650 (1966).

¹³⁵ *Ex Parte Virginia*, 100 U.S. 339, 345 (1879). The power conferred to Congress by Section Five of the Fourteenth Amendment has not been dormant. Recently, Congress used this power to enact the Religious Freedom Restoration Act of 1993, 42 U.S.C. § 22000bb et. seq. (Supp. 1995).

¹³⁶ U.S. Const. Art. 1, § 8, cl. 3.

¹³⁷ See, e.g., *Federal Energy Regulatory Comm'n v. Mississippi*, 456 U.S. 742 (1982); *Fry v. United States*, 421 U.S. 64842 (1976); *Katzenbach v. McClung*, 379 U.S. 294 (1964); *Wickard v. Filburn*, 317 U.S. 111 (1942).

FEDERAL PUNITIVE DAMAGES REFORM IS NEEDED

Punitive damages are quasi-criminal in nature; they are awarded to punish, not to compensate for harm.¹³⁸ This fact is often obscured by opponents of punitive damage reform. Punitive damages developed out of English law to aid the criminal law. The focus was, and should be on, conduct so deserving of condemnation that it should be subject to criminal punishment. Punitive damages are not intended to compensate people to “make them whole” for something they have lost; that purpose is accomplished by compensatory damages, which provide compensation for both economic losses (e.g., lost wages, medical expenses, substitute domestic services) and noneconomic losses (e.g., “pain and suffering”). Nevertheless, unlike the criminal law system, in many states there are virtually no standards for when punitive damages may be awarded—so good behavior is often swept in with the bad—and there are no clear guidelines as to the appropriate amount of punitive damages. The result is uncertainty and instability, due process violations, and a chilling effect on economic growth and innovation.¹³⁹

The problem of punitive damages “run wild” is illustrated by the litigation involving the drug Bendectin, an anti-nausea morning sickness drug once marketed by Merrell Dow Pharmaceuticals, Inc.¹⁴⁰ Although the drug had been and still is approved by the Food and Drug Administration and widely acclaimed by health care professionals worldwide, Merrell Dow withdrew Bendectin from the market in 1983, in part from concerns about punitive damages liability. Merrell Dow has never lost a final judgment in any Bendectin case in the twenty year history of the litigation; trial judges often dismiss these cases prior to trial.¹⁴¹ The lack of any meaningful standards, however, has resulted in some substantial punitive damages verdicts, which eventually have been overturned by trial courts or on appeal.¹⁴² On April 4, 1995, the Senate Commerce Committee heard compelling testimony from Representative James Bilbray concerning a personal family tragedy that possibly could have been avoided if Bendectin had not been improperly forced off the market.

The inappropriate chilling effect of punitive damages is not unique to Bendectin. A Kansas jury imposed punishment against

¹³⁸ See, e.g., Small Business Job Protection Act of 1996, Pub. L. No. 104-188 (providing, among other things, that punitive damages received in personal injury cases are subject to federal income tax); *O’Gilvie v. United States*, 117 S. Ct. 452 (1996) (punitive damages received in tort suits are subject to federal income tax, because they do not represent damages received “on account of personal injuries or sickness” and, therefore, are not excluded from taxable “gross income”).

¹³⁹ See generally Bruce Kuhlik and Richard Kingham, “The Adverse Effects Of Standardless Punitive Damage Awards On Pharmaceutical Development And Availability,” 45 Food Drug Cosm. L.J. 693, 693 (1990) (“There is a growing body of evidence that the threat of punitive damages deters the development and marketing of beneficial products”).

¹⁴⁰ In another example of punitive damages “run wild,” a New York jury in a 1994 product liability case awarded \$18 million to each of the three plaintiffs by looking to the Hebrew symbol for “life,” which has come to be associated with the number eighteen. See *Conboy v. Owens-Corning Fiberglas Corp.*, 113070/93; *Orecchia v. Owens-Corning Fiberglas Corp.*, 113071/93; *Heltzer v. Owens-Corning Fiberglas Corp.*, 4393/89 (Sup. Ct., New York Co., verdict Jan. 27, 1994). The award was reduced by the trial judge and the cases were later settled for an undisclosed amount.

¹⁴¹ See, e.g., *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir. 1995) (on remand from U.S. Supreme Court); *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 736 F. Supp. 737 (E.D. Ky. 1990), aff’d, 959 F.2d 1349 (6th Cir.), cert. denied, 113 S. Ct. 84 (1992).

¹⁴² See, e.g., *Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir.) (overturning \$75 million punitive damages award), cert. denied, 498 U.S. 950 (1990).

the manufacturer of the Sabin oral polio vaccine, because the company had not used a version of polio vaccine that had been abandoned for general use in the United States for over two decades.¹⁴³ There, the Kansas Supreme Court, by the slimmest of margins, one vote, reversed an \$8 million punitive damages verdict. One vote the other way and American children could have lost access to the Sabin polio vaccine, because of the threat posed to its manufacturer by runaway punitive damages.

The sheer unpredictability of the current system has also resulted in overdeterrence. A Conference Board Study of corporate executives found that fear of liability suits had prompted thirty-six percent of the firms to discontinue a product and thirty percent to decide against introducing a new product.

The serious problems described are supported by empirical evidence. A recent study by the Texas Public Policy Foundation found explosive increases in both the frequency of punitive damages awards and their size. From the early 1980s to the early 1990s, the total number of punitive damages awards in Dallas County was fourteen times greater, and the average award, adjusted for inflation, was nineteen times higher. In Harris County (Houston), total awards were up twenty-six fold and the average award was up eightfold.¹⁴⁴

Similarly, a 1987 study by the Institute for Civil Justice found that the average punitive award in Cook County (Chicago), Illinois, between 1965 and 1969, was \$43,000. Between 1980 and 1984, it was \$729,000—an increase of about 1,500 percent or seventeen times over twenty years.¹⁴⁵

As retired Supreme Court Justice Lewis Powell has written: “It is long past time to bring the law of punitive damages into conformity with our notions of just punishment.”¹⁴⁶ Clear, rational rules are needed to protect fundamental constitutional rights, remove barriers to interstate commerce, and promote economic growth and innovation, while at the same time providing incentives for responsible manufacturing practices.

THE PUNITIVE DAMAGES PROVISIONS IN THE ACT FIND STRONG SUPPORT

Consistent with the Supreme Court’s recognition that punitive damages are a form of punishment, the Act provides the fundamen-

¹⁴³ See *Johnson v. American Cyanamid Co.*, 718 P.2d 1318 (Kan. 1986).

¹⁴⁴ Opponents of punitive damages reform frequently cite a 1992 study by Professor Michael Rustad of Suffolk University Law School in Boston, financed by the Roscoe Pound Foundation, to argue that punitive damages awards are rare. The Rustad Study found 355 punitive damages awards in product liability cases between 1965 and 1990. These groups, however, never acknowledge what Professor Rustad said on page two of his report: “The actual number of punitive damages awards in product liability litigation is unknown and possibly unknowable because no comprehensive recording system exists.” (Emphasis added).

¹⁴⁵ Another argument frequently heard from opponents of punitive damages reform is that the handful of headline-grabbing damage awards are often reduced on appeal. True, but only after huge legal costs, lost production time, and a threat to the business’s basic credit, solvency and reputation. Those opposing reform also ignore the fact that approximately ninety-five percent of product liability cases are settled out of court and not subject to appeal. In many of these cases, the threat of punitive damages is abused as a “wild card” to force extortionate settlements. In approximately eighteen states, punitive damages are not insurable. Thus, a small business is subject to unwarranted pressure to settle a case for compensatory damages, which are insurable because a punitive damages award could end the business.

¹⁴⁶ Lewis Powell, “The ‘Bizarre’ Results of Punitive Damages,” *The Wall St. J.*, Wed., Mar. 8, 1995, at A21.

tals that are part of any criminal punishment: a definition of the “crime” by establishing a level of proof necessary for punishment, making the sentence fit the “crime,” and appropriate procedures to reduce the likelihood of a judgment unfairly based on prejudice or bias. At present, punitive damages laws in many states fail these requirements, as evidenced by the United States Supreme Court’s observation that punitive damages awards in this country have “run wild.”

DEFINING THE “CRIME”

The Act permits punitive damages to be awarded upon proof that the defendant violated the standard of “conscious, flagrant indifference to the rights or safety of others.”¹⁴⁷ This standard, which is to be applied uniformly in all product liability cases where State law provides for the award of punitive damages, reflects the quasi-criminal nature of punitive damages and is similar to the standards of many states.¹⁴⁸ The standard conveys that punitive damages are to be awarded, not for mere negligence or conduct where significant compensatory damages may be awarded, but only in serious cases of outrageous misconduct.

The Act explains how a claimant must prove the “crime” and requires that the proof be “clear and convincing.”¹⁴⁹ The standard recognizes the quasi-criminal nature of punitive damages by taking a middle ground between the burden of proof standard ordinarily used in civil cases (i.e., proof by a “preponderance of the evidence”) and the criminal law standard (i.e., proof “beyond a reasonable doubt”).¹⁵⁰

A burden of proof of “clear and convincing evidence” is now law in thirty states and the District of Columbia.¹⁵¹ This burden of proof has been recommended by each of the principal academic

¹⁴⁷ To be “conscious” of its flagrant misconduct, a defendant must be aware that its product is legally defective and that its conduct in selling it in such a condition is therefore improper. Mere consciousness that its product is dangerous, that it can or indeed probably will cause substantial harm or even death, is insufficient by itself, since manufacturers, sellers, renters and lessors of many dangerous products—such as cars, power saws, and chemicals—surely are fully conscious of the inherent dangers in their products. It is only when a defendant consciously leaves in its product a danger that is unreasonable and known to be defective, that its conduct can be said to manifest a “conscious, flagrant indifference” to the safety of others.

¹⁴⁸ See, e.g., Ky. Rev. Stat. Ann. § 411.184(2) (Baldwin 1991) (“flagrant indifference to the rights of plaintiff and with a subjective awareness. . .”); N.J. Rev. Stat. Ann. § 2A:58C-5a (West 1987) (“reckless indifference” to consequences); Ohio Rev. Code Ann. § 2307.80(A) (Page 1991) (“flagrant disregard”).

¹⁴⁹ “Clear and convincing evidence” is defined in section 101(3).

¹⁵⁰ See Malcolm Wheeler, *The Constitutional Case for Reforming Punitive Damage Procedures*, 69 Va. L. Rev. 269, 298 (1983).

¹⁵¹ See Ala. Code § 6-11-20 (1993); Alaska Stat. § 09-17-020 (1994); Cal. Civ. Code § 3294(a) (West 1970 & Supp. 1995); Ga. Code Ann. § 51.12-5.1 (Supp. 1995); 735 ILCS 5/2-1115.05(b) (1995); Iowa Code Ann. § 668A.1 (West 1987); Kan. Stat. Ann. § 60-3701(c) (1994); Ky. Rev. Stat. Ann. § 411.184(2) (Michie/Bobbs-Merrill 1992); Minn. Stat. Ann. § 549.20 (West 1988 & Supp. 1995); Miss. Code Ann. § 11-1-65(1)(a) (Supp. 1995); Mont. Code Ann. § 27-1-221(5) (1995); N.J. Stat. Ann. § 2A:15-5.12 (1995); Nev. Rev. Stat. Ann. § 42-005(1) (1991); N.C. H.B. 729 (effective Jan. 1, 1996); N.D. Cent. Code § 32-03-2-11 (Supp. 1995); Ohio Rev. Code Ann. § 2307.80(A) (Anderson 1991); Okla. Stat. Ann. tit. 23, § 9.1 (West Supp. 1995); Or. Rev. Stat. § 18.537 (1995); S.C. Code Ann. § 15-33-135 (Law. Co-op. Supp. 1995); S.D. Codified Laws Ann. § 21-1-4.1 (1987); Tex. S.B. 25 (effective Sept. 1, 1995); Utah Code Ann. § 78-18-1 (1992); *Linthicum v. Nationwide Life Ins. Co.*, 723 P.2d 675 (Ariz. 1986); *Jonathan Woodner, Co. v. Breeden*, 665 A.2d 929 (D.C. 1995); *Masaki v. General Motors Corp.*, 780 P.2d 566 (Haw. 1989); *Travelers Indem. Co. v. Armstrong*, 442 N.E.2d 349 (Ind. 1982); *Tuttel v. Raymond*, 494 A.2d 1353 (Me. 1985); *Owens-Illinois v. Zenobia*, 601 A.2d 633 (Md. 1992); *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896 (Tenn. 1992); *Wangen v. Ford Motor Co.*, 294 N.W.2d 437 (Wis. 1980); *Rodriguez v. Suzuki Motor Corp.*, 936 S.W.2d 104 (Mo. 1996) (en banc). One state, Colorado, requires proof beyond a reasonable doubt in punitive damages cases. See Colo. Rev. Stat. § 13-25-127(2) (1987).

groups to analyze the law of punitive damages since 1979, including the American Bar Association, the American College of Trial Lawyers, and the National Conference of Commissioners on Uniform State Laws in 1996.¹⁵² The Supreme Court has specifically endorsed requiring “clear and convincing evidence” for the award of punitive damages.¹⁵³

MAKING THE SENTENCE FIT THE “OFFENSE”

The Act puts reasonable parameters on “sentencing” to make it fit the “offense.” Proportionality has been an important part of the Supreme Court’s consideration of the validity of criminal punishment.¹⁵⁴ Even very serious crimes such as larceny, robbery, and arson have sentences defined with a maximum set forth in a statute.¹⁵⁵

The Act sets forth the presumptive maximum “sentence” against larger businesses as two times the sum of a plaintiff’s compensatory damages (i.e., economic loss plus noneconomic loss), or \$250,000, whichever is greater. It also recognizes that smaller businesses and organizations, as well as individuals, need special protection from punitive damages. The Act, therefore, sets forth the maximum “sentence” against an individual whose net worth does not exceed \$500,000 or against an owner of an unincorporated business, or any partnership, corporation, association, unit of local government, or organization which has fewer than twenty-five full-time employees, as the lesser of two times the amount awarded to the claimant for compensatory damages, or \$250,000 (i.e., \$250,000 is the maximum).

In cases involving larger businesses, a judge may choose not to apply the presumptive statutory limit and may award punitive damages up to the amount of the jury verdict, but never above the jury award, if the “proportionate” award is found to be “insufficient to punish the egregious conduct of the defendant.”

If State law further limits the amount of punitive damages which may be awarded, those limits are not preempted by this Act.

The general approach used in the Act to prevent runaway verdicts and achieve proportionality in punitive damages awards is modeled after a proposal by the American College of Trial Law-

¹⁵²See American Bar Association, Special Committee on Punitive Damages of the American Bar Association, Section on Litigation, *Punitive Damages: A Constructive Examination* 19 (1986) [hereinafter ABA Report]; American College of Trial Lawyers, Report on Punitive Damages of the Committee on Special Problems in the Administration of Justice 15-16 (1989) [hereinafter ACTL Report]; American Law Institute, 2 *Enterprise Responsibility for Personal Injury—Reporters’ Study* 248-49 (1991) [hereinafter ALI Reporters’ Study]; National Conference Of Commissioners On Uniform State Laws, *Uniform Law Commissioners’ Model Punitive Damages Act* § 5 (approved on July 18, 1996) [hereinafter Uniform Law Commissioners’ Model Punitive Damages Act].

¹⁵³See *Pacific Mutual Life Ins. Co.*, 499 U.S. at 23 n.11 (stating that “there is much to be said in favor of a state’s requiring, as many do, . . . a standard of ‘clear and convincing evidence’”).

¹⁵⁴See, e.g., *Harmelin v. Michigan*, 501 U.S. 957 (1991); *Solem v. Helm*, 463 U.S. 277 (1983); *Hutto v. Davis*, 454 U.S. 370 (1982); *Rummel v. Estelle*, 445 U.S. 263 (1980).

¹⁵⁵Some examples of federal criminal fines, even for particularly egregious crimes, do not exceed \$250,000 and include: tampering with consumer products (\$100,000, if death results); retaliation against a witness (\$250,000); assault on the President (\$10,000); bank robbery (\$10,000, with the use of a deadly weapon); sexual exploitation of children (\$100,000 for an individual, \$200,000 for an organization); and treason (\$10,000).

yers,¹⁵⁶ a respected organization of experienced plaintiff and defense trial attorneys. Other “mainstream” academic groups have likewise recommended that punitive damages be awarded in some ratio to actual damages.¹⁵⁷ Approximately one-quarter of the States have set forth guidelines, including Illinois, Indiana, North Carolina, New Jersey, Oklahoma, Texas in 1995, Ohio in 1996, and Alaska in 1997.¹⁵⁸

Permitting the award of punitive damages up to a proportion of a plaintiff’s actual damages, coupled with an alternative monetary ceiling, is the fairest and most flexible of the various attempts to place parameters on the size of punitive damages awards. This flexible approach accomplishes punishment and deterrence even in the unusual situation where there is serious misconduct but relatively minor actual damages. Federal antitrust laws have worked well for decades with punishment set in proportion to actual losses. They are a solid model for appropriate punishment.

ARGUMENTS CHALLENGING PROPORTIONALITY ARE UNSUPPORTED

It has been argued that proportionality may result in inadequate deterrence. As Thomas Jefferson noted, however, over two hundred years ago, “if the punishment were only proportional to the injury, men would feel it their inclination as well as their duty to see the laws observed.”¹⁵⁹

¹⁵⁶See ACTL Report at 15 (proposing that punitive damages be awarded up to two times a plaintiff’s compensatory damages or \$250,000, whichever is greater). The ACTL approach also provides that the jury is not to be informed of the limit on punitive damages, and that the limit is to be applied by the judge after the case. This is the approach followed in some states, among them Virginia. See Va. Code Ann. § 8.01-38.1 (1994).

¹⁵⁷See ABA Report at 64-66 (recommending that punitive damages awards in excess of three-to-one ratio to compensatory damages be considered presumptively “excessive”); ALI Reporters’ Study at 258-59 (endorsing concept of ratio coupled with alternative monetary ceiling).

¹⁵⁸See Alaska H.B. 58 § 9.17.020(f)-(h) (signed by Governor May 9, 1997; punitive damages limited to three times amount of claimant’s compensatory damages of \$500,000, whichever is greater; but in cases involving actual malice, punitive damages may be awarded up to four times the amount of claimant’s compensatory damages, or four times the aggregate amount of financial gain that the defendant received as a result of its conduct, or \$7 million, whichever is greater); Ohio Am. Sub. H.B. No. 350 § 2315.21 (signed by governor 1996) (limits amount of punitive damages recoverable from all parties except large employers to the lesser of three times the amount of compensatory damages awarded to the plaintiff or \$100,000 and limits the amount of punitive damages recoverable from large employers to the greater of three times the amount of compensatory damages awarded to the plaintiff or \$250,000); Ill. Ann. Stat., ch. 735 § 5/2-1115.05 (Smith-Hurd 1995) (punitive damages limited to three times amount of claimant’s economic damages); Ind. Code Ann. § 634-4-34-5 (1995) (limits punitive damages to the greater of three times actual damages or \$50,000); N.C. Gen. Stat. § 1D-25 (1995) (punitive damages limited to three times amount of claimant’s compensatory damages or \$250,000, whichever is greater); Tex. Civ. Prac. & Rem. Code Ann. § 41.008 (West 1995) (limits punitive damages awards to \$200,000 or two times economic damages plus an amount equal to any noneconomic damages up to \$750,000); N.J. Stat. Ann. § 22A:15-5.14 (West 1995) (punitive damages limited to five times amount of claimant’s compensatory damages or \$350,000, whichever is greater); Nev. Rev. Stat. § 42.005 (1991) (punitive damages awards permitted up to \$300,000 in cases where compensatory damages are less than \$100,000 and to 3 times the amount of compensatory damages in cases of \$100,000 or more); N.D. Cent. Code § 32.03.2-11(4) (1995) (permitting punitive damages up to twice compensatory damages, or \$250,000, whichever is greater); Conn. Gen. Stat. § 52-204a (West Supp. 1992) (punitive award permitted up to twice the compensatory damages); Fla. Stat. Ann. § 768.73(1)(b) (West Supp. 1992) (punitive damages may be awarded up to 3 times compensatory damages unless “clear and convincing evidence” is presented by the plaintiff to show that a higher award is not excessive); Kan. Stat. Ann. § 60-3701 (1995) (punitive damages in general shall not exceed the annual gross income earned by the defendant based on the defendant’s highest gross income earned for any one of the five years immediately before the act for which such damages are awarded, or \$5 million, whichever is less); Colo. Rev. Stat. § 13-21-102(1)(a)(1987) (punitive award may not exceed compensatory damages); Okla. S.B. 263 (punitive damages generally permitted up to amount of compensatory damages awarded) (effective Aug. 25, 1995); Va. Code Ann. § 8.01-38.1 (1994) (punitive damages permitted up to a maximum of \$350,000).

¹⁵⁹Thomas Jefferson, “A Bill for Proportioning Crimes and Punishment in Cases Heretofore Capital,” 1779, in “Papers of Thomas Jefferson,” 2:492, 493 (Julian P. Boyd ed. 1950).

Furthermore, it should be remembered that there is no limit on the number of times a party can be punished under the Act and that when a person engages in wrongful conduct, he or she does not know how many people will be hurt and how much harm might occur. Thus, there is simply no way for a defendant to determine in advance the actual damages of all persons who may be injured by its conduct.

One must also remember that compensatory damages in many product liability cases run very high. Accordingly, the Act's approach to proportionality in punitive damages awards for larger businesses (i.e., the greater of two times a claimant's total compensatory damages or \$250,000) would permit the imposition of substantial punitive damages. For example, in a June 1996 case involving a driver injured in an automobile accident, an Alabama jury awarded \$50 million in compensatory damages and \$100 million in punitive damages. The automobile's manufacturer argued that the plaintiff had been intoxicated and lost control of his car after falling asleep at the wheel.¹⁶⁰ In July 1995, a Missouri jury awarded a total of \$350 million to the family of a pilot killed in a helicopter crash against the French manufacturer of the helicopter's engine. The award consisted of \$175 million in compensatory damages and \$175 million in punitive damages.¹⁶¹ Numerous other examples of product liability cases involving large compensatory damages exist in the case law.¹⁶²

It has also been argued that totally unlimited punitive damages are needed to police corporate wrongdoing. This assertion is not supported by fact. There is no credible evidence that the behavior of corporations, individuals, or others is less safe in either those states that have set limits on punitive damages or in the six states (Louisiana, Nebraska, Washington, New Hampshire, Massachusetts, and Michigan)¹⁶³ that do not permit punitive damages at all. Some have argued that plaintiffs could find it difficult to obtain legal representation if punitive damages are limited, but plaintiffs in these states have no more difficulty obtaining legal representation than in those states where the "sky is the limit."

Finally, it has been argued that the proportionality requirement in section 108 is unfair to women and others groups, who allegedly "rely more heavily on noneconomic damages to receive compensation for injuries." First, this argument misapprehends the basic

¹⁶⁰ See *Hardy v. General Motors Corp.*, CV-93-56 (Ala. Cir. Ct., Lowndes Co., verdict June 3, 1996).

¹⁶¹ See *Barnett v. La Societe Anonyme Turbomeca France*, CV-93-24644 (Mo. Cir. Ct., Jackson Co., verdict July 20, 1995).

¹⁶² See, e.g., *Letz v. La Societe Anonyme Turbomeca France*, No. CV93-19156 (Mo. Cir. Ct. 1995) (\$70 million compensatory award to family of woman who died when defective helicopter crashed. No punitive damages available in wrongful death cases in Missouri); *Eimers v. Honda Motor Co.*, No. 90-25 (W.D. Pa. 1993) (\$19.7 million compensatory award to man injured when sidestand on motorcycle caught on ground during turn); *Ketchum v. Hyundai Motor Co.*, No. VC 004170 (Cal. Super. Ct. Los Angeles Cty. 1993) (\$15 million compensatory award to boy in case involving defective seat belt); *General Chemical Corp v. De La Lastra*, No. D-1799 (Texas Sup. Ct. 1993) (\$14.6 million compensatory award to family of two brothers asphyxiated while spreading a sulfite-based chemical on shrimp catch); *Lopez v. Westinghouse*, No. 8508 (Texas Dist. Ct., 229th Jud. Dist., 1991) (\$13 million compensatory award to family of man electrocuted while working on a defective piece of equipment); *Allman v. Sears, Roebuck & Co.*, 1989 U.S. Dist. LEXIS 11897 (E.D. Pa. 1989) (\$10 million compensatory award to plaintiff injured in case involving defective propane tank).

¹⁶³ Michigan permits "exemplary" damages as compensation for mental suffering consisting of a sense of insult, indignity, humiliation, or injury to feelings, but does not permit punitive damages for purposes of punishment. See *Wise v. Daniel*, 190 N.W.2d 746 (Mich. 1992).

premise that punitive damages have absolutely nothing to do with compensating an individual for a loss—punitive damages are used for the social purpose of punishing the defendant and deterring similar wrongful conduct and as such they are purely a “windfall” to the claimant. Second, women plaintiffs who work in the home, children and the elderly have “economic losses” that do not show up in Bureau of Labor Statistics data and which are readily recovered in punitive damage actions.¹⁶⁴ These arguments also ignore women in business, particularly small businesses, whose entire enterprise is threatened by out of control punitive damages.¹⁶⁵

JUDICIAL POWER TO AWARD PUNITIVE DAMAGES UP TO AMOUNT OF JURY VERDICT IN CIRCUMSTANCES MANIFESTING EGREGIOUS CONDUCT

In a case involving a larger business, the Act allows a judge to choose not to apply the presumptive statutory limit and award punitive damages up to the amount of the jury verdict, but never above the jury award. The judge may do this if the “proportionate” award is “insufficient to punish the egregious conduct of the defendant.” The Act lists a number of factors that judges are to consider when making this determination, but the judge is not required to find all of them to award an additional amount of punitive damages. The trial court must articulate its reasons for utilizing this exception to the rule limiting punitive damages in findings of fact and conclusions of law. Research by the United States Department of Justice indicates that the provision does not violate the right to trial by jury in civil cases found in the Seventh Amendment to the United States Constitution.¹⁶⁶

BIFURCATION

“Bifurcation” is a procedure that permits a trial to be divided into two segments, the first addressing compensatory damages, the second dealing with punitive damages. Judicial economy is achieved by having the same jury determine both compensatory damages and punitive damages issues.

The Act provides for bifurcation at the request of any party in a case alleging punitive damages. It permits either party to request that the trier of fact conduct a separate proceeding to determine whether punitive damages are to be awarded for the harm that is the subject of the action and the amount of the punitive award. The Act also provides that, in such a proceeding, evidence relevant only to the claim of punitive damages, as determined by state law, shall be inadmissible in any proceeding to determine whether com-

¹⁶⁴In the case of children, economists are frequently used at trial to provide testimony based on income and work-life expectancy data generated by the federal government as to economic loss. The same is true of women and the elderly, where the focus is on the economic value of services these persons provide and the cost to employ substitute domestic services, which can be quite high.

¹⁶⁵A U.S. Small Business Administration study has predicted that women will own forty percent of all small businesses by the year 2000. In addition, Paul Huard, Senior Vice President of the National Association of Manufacturers (NAM), testified before the House Commerce Committee in February 1995 that smaller firms will benefit most from product liability and punitive damages reform, because they are least able to absorb the outrageous costs of the current product liability system.

¹⁶⁶See Cong. Record, May 9, 1995, S6328–29. For purposes of severability analysis, sections 108(b)(1) and 108(b)(3) are to be considered nonseverable; section 108(b)(2) contains a special rule for smaller businesses which is severable from sections 108(b)(1) and 108(b)(3).

pensatory damages are to be awarded. The “bifurcated trials” provision is to be applied uniformly in all product liability cases.

Bifurcated trials are equitable, because they prevent evidence that is highly prejudicial and relevant only to the issue of punitive damages (i.e., the wealth of the defendant) from being heard by jurors and improperly considered when they are determining basic liability. Bifurcation also helps jurors “compartmentalize” a trial, allowing them to separate and understand the difference in the burden of proof that is required for compensatory damages awards (i.e., proof by a preponderance of the evidence) from the higher burden of proof (i.e., proof by clear and convincing evidence) that is required under the Act to support liability for punitive damages.

Recognizing the benefits of bifurcation, some courts have recently adopted the procedure as a matter of common law reform.¹⁶⁷ Other states have made similar changes through court rules or legislation.¹⁶⁸ This reform is supported by the American Law Institute’s Reporters’ Study, the American Bar Association, the American College of Trial Lawyers, and the National Conference of Commissioners on Uniform State Laws.¹⁶⁹

PREEMPTION

The Act does not create a cause of action for punitive damages or provide for recovery of punitive damages in those States where such damages do not exist. The Act does create a uniform standard of liability for punitive damages where punitive damages would otherwise be available under state law. The Act also requires the uniform use of the “bifurcated trials” procedures described above. However, nothing in the Act preempts or supersedes any State or Federal law that would further limit the amount of punitive damages that may be awarded. Since section 108 does not preempt State laws that would further limit the award of punitive damages, if the application of otherwise applicable State law would result in a lower amount of punitive damages than would application of section 108, the State law would apply. Similarly, the “additional amount” provision (section 108(c)) applies only to the calculation of punitive damages under Federal law, and does not affect the application of otherwise applicable State law regarding punitive damages. Furthermore, nothing in this Act shall modify or reduce the ability of courts to order remittiturs.

Section 108(a) establishes a uniform standard of liability for punitive damages. It provides that punitive damages may be awarded, to the extent permitted by applicable state law, if the claimant establishes by “clear and convincing evidence” that the harm that is the subject of the action was carried out by the defendant with a “conscious, flagrant indifference to the rights or safety of others.”

¹⁶⁷ See *Transportation Ins. Co. v. Moriel*, 879 S.W.2d 10 (Tex. 1994); *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896 (Tenn. 1992).

¹⁶⁸ See Cal. Civ. Code § 3295(d) (West Supp. 1993); Miss. H.B. 1270 § 2(1)(b) (signed by governor Feb. 18, 1993); Minn. Stat. Ann. § 549.20 (West Supp. 1993); Mont. Code Ann. § 27-1-221(7) (1991); Nev. Rev. Stat. § 42.005(3) (1991); N.J. Stat. Ann. § 2A:58C-5(b) (West 1987); N.D. Cent. Code § 32-03.2-11(2)-(3) (signed by governor Mar. 31, 1993); Utah Code Ann. § 78-18-1(2) (1992).

¹⁶⁹ See ABA Report at 19; ACTL Report at 18-19; ALI Reporters’ Study at 255 n.41; Uniform Law Commissioners’ Model Punitive Damages Act at § 11.

Section 108(b) requires that the punitive damage award be proportional to the harm caused. Section 108(b)(1) provides that the amount of punitive damages that may be awarded for a claim against a larger business is two times the amount of the plaintiff's compensatory damages, or \$250,000, whichever is greater. Section 108(b)(2) provides that the maximum amount of punitive damages recoverable against an individual whose net worth does not exceed \$500,000 or against an owner of an unincorporated business, or any partnership, corporation, association, unit of local government, or organization which has fewer than twenty-five full-time employees, shall not exceed the lesser of two times the amount awarded to the claimant for compensatory damages, or \$250,000.

Section 108(b)(3) sets forth an exception to the limitation on punitive damages awards contained in section 108(b)(1). Section 108(b)(3)(A) allows a judge to award punitive damages against a larger business up to the amount of the jury verdict when the "proportionate" award is "insufficient to punish the egregious conduct of the defendant. . . ." Section 108(b)(3)(B) lists a number of factors that judges are to consider when making this determination, but the judge is not required to find all of them to award an additional amount of punitive damages. Section 108(b)(3)(C) states that, if a trial court awards punitive damages beyond the statutory limit, it shall articulate its reasons in findings of fact and conclusions of law. Section 108(b)(3)(D) states that the Act does not create a cause of action for punitive damages or provide for recovery of punitive damages in those States where such damages do not exist. It also does not preempt or supersede any State or Federal law to the extent that such law would further limit the amount of a punitive damages award. Furthermore, nothing in the Act modifies or reduces the ability of courts to order remittiturs.

Section 108(c) permits either party to request that the trier of fact conduct a separate proceeding to determine whether punitive damages are to be awarded for the harm that is the subject of the action and the amount of the award. Section 108(c) also provides that, in such a proceeding, evidence relevant only to the claim of punitive damages, as determined by state law, shall be inadmissible in any proceeding to determine whether compensatory damages are to be awarded.

Section 109—Liability for certain claims relating to death

Alabama's system for the recovery of damages in civil actions relating to death is unique among the States. Unlike every other State, Alabama's wrongful death statute,¹⁷⁰ as interpreted, provides for only punitive damages in wrongful death cases.¹⁷¹ Compensatory damages are not available in Alabama wrongful death actions. As a result, Senators Heflin and Shelby of Alabama argued during floor debate in the 104th Congress,¹⁷² that Alabama wrong-

¹⁷⁰ See Ala. Code §§ 6-5-391, 6-5-410 (1993 Repl. Vol.).

¹⁷¹ See, e.g., *Deaton, Inc. v. Burroughs*, 456 So. 2d 771, 776 (Ala. 1984). Under current Alabama law, the product liability wrongful death plaintiff need not show wanton, reckless, or intentional conduct, but merely the same proof required to make out a standard negligence or Alabama Extended Manufacturer's Liability Doctrine claim. Evidence of loss of earnings, loss of enjoyment of life, and contributions to family are inadmissible, because they are irrelevant.

¹⁷² See Cong. Record, May 9, 1995, S6325-27.

ful death claimants could be adversely affected by the punitive damages reforms section of the Act.

To accommodate the immediate special needs of Alabama wrongful death claimants, the Act permits Alabama's wrongful death law to continue unaffected by the punitive damages reforms in the Act until September 1, 1997. The Act will, therefore, allow the Alabama legislature an adequate opportunity to amend its wrongful death statute to conform with the approach used by every other State.

Section 109 provides that in any civil action in which the alleged harm to the claimant is death and, as of the effective date of this Act, the applicable State law provides, or has been construed to provide, for damages only punitive in nature (i.e., if the case involves an Alabama wrongful death claim), a defendant may be liable for any such damages without regard to section 108, but only during such time as the State law so provides. Section 109 shall cease to be effective on September 1, 1997, or on the effective date of legislation amending Alabama's wrongful death statute, whichever is earlier.

Section 110—Several liability for noneconomic loss

The Act adopts the "California rule," which holds defendants liable for their "fair share" of responsibility for noneconomic loss, such as pain and suffering.

The concept of "fair share," or several, liability sounds self-evident to most people. Most states, however, give expression in their law to the principle of joint ("deep pocket") liability which, in its unrestrained form, means that a defendant who is found only one percent at fault can be burdened with an entire damages award.²⁰² This system is unfair and blunts incentives for safety, because it allows negligent actors to under-insure and puts full responsibility on those who may have been only marginally at fault. Thus, a jury's specific finding that a defendant is minimally at fault gets overridden and the minor player in the lawsuit bears an unfair and costly burden.

Joint liability has produced extreme and unwanted consequences. It has caused suppliers of raw materials, often "deep pockets," to refuse to supply critical raw materials to manufacturers of medical devices and other needed products, such as protective sporting goods equipment.

Julie Nimmons, President and Chief Executive Officer of Schutt Sports Group in Litchfield, Illinois, one of two remaining U.S. man-

²⁰² For example, in *Walt Disney World Co. v. Wood*, 515 So. 2d 198 (Fla. 1987), Disney was required to pay an entire damages award, even though it was only one percent at fault for the claimant's harm. The rationale for making a defendant who is only one percent at fault pay 100 percent of damages is due to something called, "risk distribution." The theory is that a wealthy defendant is better able to distribute the cost of a risk of injury than an injured plaintiff is able to absorb it. The "risk distribution" rationale supports the idea of allowing joint liability for economic losses, loss of wages, medical costs, or many other economic costs that an injured person may sustain. It does not, directly or indirectly, support a law that would require someone who is only one percent at fault to pay 100 percent damages for pain and suffering or other such noneconomic losses. The law of workers' compensation is an excellent example. That is a "risk distribution" mechanism. The losses that are paid under that mechanism, however, are economic losses, not damages for pain and suffering.

ufacturers of football helmets,²⁰³ testified in September 1993 about a baseball safety product that her company did not make because no raw material supplier would accept the potential liability of supplying components for the new safety product.²⁰⁴

On March 4, 1997, Ms. Nimmons testified that her company would like to market protective head gear for hockey players to meet the rapidly growing interest in the sport in the United States, but the current product liability system deters her from doing so.²⁰⁵ Committees in both the Senate and the House of Representatives have received numerous testimonies about similar experiences by other individuals during the decade and a half Congress has considered the issue of product liability reform legislation.²⁰⁶

Recognizing the need for joint liability reform, approximately thirty-three states have abolished or modified the principle of joint liability.²⁰⁷ They have done so, however, in a great variety of ways and, thereby, have contributed to the already serious problem of inconsistency among our nation's tort laws. (A fact that is often overlooked is that no state has repealed laws that have limited or eliminated joint liability).

The Act takes a fair and balanced approach. It follows a joint liability reform enacted in California through a ballot initiative ("Proposition 51") approved by an overwhelming majority of voters in 1986.²⁰⁸ The Act permits the States to apply the rule of joint liability for economic damages (e.g., medical expenses and lost wages and the cost of substitute domestic services in the case of injury to a homemaker), so that claimants can recover full compensation for these losses.²⁰⁹ On the other hand, it eliminates joint liability for "noneconomic damages" (e.g., damages for pain and suffering or emotional distress). This means that each defendant will be liable for damages for pain and suffering in an amount proportional to its share of fault. The provision does not set any "caps" or "limits" on noneconomic losses.

In applying section 110, the trier of fact is to apportion responsibility for a claimant's harm in reference to all persons responsible for the injury, whether or not such person is a party to the product

²⁰³In 1988, Rawlings Sporting Goods decided to stop manufacturing or selling football helmets. Rawlings was the 18th manufacturer to discontinue the manufacture of this product, joining Hutch, Spaulding, Wilson and MacGregor. According to Riddell, Inc., one of two remaining U.S. helmet manufacturers, half of the cost of a football helmet goes to liability-related expenses.

²⁰⁴Testimony of Ms. Julie Nimmons, hearing of the Consumer Subcommittee, Senate Committee on Commerce, Science and Transportation, September 23, 1993, S. Hrg. 103-490, at 20.

²⁰⁵Testimony of Ms. Julie Nimmons, hearing of the Senate Committee on Commerce, Science and Transportation, March 4, 1997, at 2.

²⁰⁶For example, Mary Kaynor, counsel for the Risk Management Foundation at Harvard Medical Institutions, testified before the Senate Small Business Committee in November 1991 that her foundation, which sponsors medical research products, is discouraged from dealing with small businesses because they fear that the foundation will become the "deep pocket" in the event of a lawsuit. This result is particularly unfortunate because small businesses are widely recognized as uniquely important to the innovative process.

²⁰⁷See Victor Schwartz, *Comparative Negligence* app. b (3d ed. 1994). The ALI Reporters' study also recommends reforming the doctrine of joint and several liability. See ALI Reporters' Study at 147.

²⁰⁸See Cal. Civ. Code Ann. § 1421.2 (West 1996). The Nebraska legislature adopted this approach in 1991 after carefully studying the issue. See Neb. Rev. Stat. § 25-21,185.10 (1989 & Cum Supp. 1994).

²⁰⁹Section 110 limits the doctrine of joint liability as applied to noneconomic damages in product liability actions. This section, however, does not preempt other limitations on joint liability with respect to economic damages, which have been imposed by individual jurisdictions. Indeed, a number of jurisdictions have enacted more sweeping reforms with respect to joint liability. These reforms are not affected by the Act.

liability action.²¹⁰ In 1992, the California Supreme Court unanimously held in *DaFonte v. Up-Right, Inc.*, 2 Cal. 4th 593, 602, 828 P.2d 140, 145 (1992), that the California law on which section 110 is based could not achieve its purpose unless read this way. The Supreme Court of Florida, in *Fabre v. Marin*, 623 So. 2d 1182, 1185 (Fla. 1993), interpreting a similar statute, held:

The only means of determining a party's percentage of fault is to compare that party's percentage to all of the other entities who contributed to the accident, regardless of whether they have been or could have been joined as defendants.

In reaching its holding, the court approvingly quoted a lower court opinion which stated:

The obvious purpose of the statute was to partially abrogate the doctrine of joint and several liability by barring its application to noneconomic damage. To exclude from the computation the fault of an entity that happens not to be a party to the proceeding would thwart this intent. *Id.* at 1184. The Act is consistent with the laws in these states.

THE "CALIFORNIA APPROACH" IS FAIR AND DOES NOT DISCRIMINATE

Some opponents of joint liability reform have argued that the California approach somehow discriminates, because women or other groups may have less economic losses than others. The California approach does not discriminate. In fact, the California Supreme Court has ruled that the California law meets equal protection guarantees found in both the California and United States Constitutions.²¹¹

Moreover, Suzelle Smith, a highly respected attorney from California who practices both for plaintiffs and defendants, testified before the Consumer Affairs Subcommittee in September 1993 and before the Senate Judiciary Committee in March 1994 that the California approach works, is fair to all groups, and is pro-consumer. She testified that, prior to the California initiative, her experience was that juries often rendered defense verdicts in cases in which a finding to the contrary could mean that a minimally at-fault defendant would be saddled with the entire damage award.

Section 110(a) limits each defendant's liability for noneconomic damages in a product liability action to that defendant's percentage of responsibility as determined by the trier of fact. In most cases the percentage determination required by this section will not be subject to an exact mathematical computation. Rather, it will be based on the common sense approximation assigned to it by the jury or by the court. In determining the percentage of each defendant's liability, the trier of fact should take into consideration the proportionate share of each party's responsibility for the total harm caused, including that portion attributable to the claimant. The

²¹⁰ Thus, the trier of fact will measure a defendant's share of fault or responsibility for the claimant's loss by references to all responsible for the claimant's loss, including defendants, third-party defendants, settled parties, non-parties, and persons or entities that cannot be tried (e.g., bankrupt persons, employers, and other immune entities).

²¹¹ See *Evangelatos v. Superior Court*, 753 P.2d 585 (Cal. 1988).

focus of the inquiry should be on the defendant's "responsibility." For example, if a defendant's share of responsibility for the harm is found to be twenty-five percent, that defendant is liable for twenty-five percent of the noneconomic damages award.

Section 110(b) provides that, for purposes of determining the amount of noneconomic loss allocated to a defendant under section 110(a), the trier of fact shall apportion responsibility for a claimant's harm in reference to all persons responsible for the injury, whether or not such person is a party to the product liability action.

TITLE II—BIOMATERIALS ACCESS ASSURANCE

Each year millions of citizens depend on the availability of implantable medical devices, such as pacemakers, heart valves, artificial blood vessels, angioplasty catheters, left ventricular assist devices, and hip and knee joints. The availability of these devices is critically threatened, because several suppliers have ceased supplying raw materials and component parts to medical implant manufacturers. Suppliers have found that the risks and costs of responding to litigation related to medical implants far exceeds potential sales revenues, even though courts are not finding suppliers liable.²¹²

For example, a 1997 study by Aronoff Associates, "Biomaterials Availability: A Vital Health Care Industry Hangs in the Balance,"²¹³ which updates a 1994 study,²¹⁴ reveals that at least seventy-five percent of suppliers of biomaterials who used to make medical implants have banned sales to U.S. implant manufacturers. Most of those that still supply are seriously evaluating whether they should continue to do so. This change reflects a forty percent drop in the percentage of suppliers willing to sell to the permanent implant market since 1994, when the first study on the biomaterials shortage was released.

The 1997 study by Aronoff Associates found that the costs and risks associated with possible claims was a key factor in every supplier's decision not to sell to the implant market. The study also found that there will be a narrowing of choices for doctors in providing the best treatment for patients as certain implant products disappear from the market. One such product documented in the study—an implant used in spinal surgery—will disappear from the market by the end of 1997. Among the component parts used in pacemakers, heart valves, and catheters, for example, that are difficult, if not impossible to obtain, are electronic components and circuitry, specialty electrical wires, films used for flexible circuitry, coloring agents, and specialty glue.²¹⁵

Consumers suffer the most from the crisis in biomaterials availability. Nine-year old Tara Ransom of Phoenix, Arizona, is one ex-

²¹² See generally Edward M. Mansfield, Reflections on Current Limits on Component and Raw Materials Supplier Liability and the Proposed Third Restatement, 84 Ky. L.J. 221, 235-37 (1995-96).

²¹³ See Aronoff Associates, Biomaterials Availability: A Vital Health Care Industry Hangs in the Balance (April 1997).

²¹⁴ See Aronoff Associates, Market Study: Biomaterials Supply For Permanent Medical Implants (March 1994).

²¹⁵ See Aronoff Associates, Biomaterials Availability: A Vital Health Care Industry Hangs in the Balance (April 1997).

ample. Tara is alive today because a brain shunt (a small plastic tube) relieves a severe medical condition, hydrocephalus—sometimes called “water on the brain.”²¹⁶ When Tara outgrows her shunt and it needs to be replaced, a replacement may not be available, because companies that supplied basic ingredients for the medical device will no longer do so.

The Subcommittee on Consumer Affairs also learned of the problems facing consumers through Peggy Phillips. Ms. Phillips is a Virginia resident who has survived two episodes of Sudden Cardiac Death Syndrome and is the recipient of a device known as an Automatic Implantable Cardioverter Defibrillator. She testified that, in the current legal environment, it did not make sense for raw materials suppliers to continue supplying device manufacturers. Ms. Phillips related that one supplier spent \$8 million annually defending itself in cases involving temporomandibular joint (TMJ) implants, even though that supplier had no role in the design, manufacture or sale of the device. Ms. Phillips noted sales by all suppliers to all TMJ implant manufacturers “totaled \$418,000 while sales of this same raw material to all other markets totaled \$282 million.”²¹⁷ In essence, suppliers will not provide their product to medical device manufacturers, because such transactions involve low returns and a high risk of very substantial legal costs.

Phyllis Greenberger, Executive Director for the Society for the Advancement of Women’s Health Research, testified that ensuring the availability of implantable medical devices is especially important to women. “Women,” she testified, are disproportionately impacted by a shortage of biomaterials “because they live longer than men, and as a result, suffer more from chronic disease, increasing their chances of needing a medical device, such as hip or joint replacements.”²¹⁸

On March 4, 1997, the Committee heard from Thomas Deuschle, from Liberty, Missouri, and Dr. Steven Gunther, Chief Resident of Orthopaedics at George Washington University Hospital in Washington, D.C.²¹⁹

Thomas Deuschle told about his daughter, Emma, who was born in 1990 with a hole in her heart, a condition known as VDS. Emma was born with an extremely low birth weight and was unable to gain weight, because her heart condition artificially elevated her metabolic rate. After several months, Emma underwent open heart surgery to have a heart patch made from Dacron® polyester material placed over the hole in her heart. Today, Emma is a healthy, happy six year old. Her father testified that it would have been a personal tragedy if the patch made of Dacron® polyester had not been available for Emma and urged passage of the biomaterials access assurance title in the current bill. DuPont, the manufacturer of Dacron®, has indicated it will no longer supply that material to manufacturers of medical devices.

²¹⁶ See Linda Ransom, *Lawyers May Kill My Daughter*, *The Wall St. J.*, March 20, 1996.

²¹⁷ Testimony of Peggy Phillips, April 4, 1995 hearing, S.Hrg. 104-435 at 196.

²¹⁸ Testimony of Phyllis Greenberger, April 4, 1995 hearing, S.Hrg. 104-435 at 213.

²¹⁹ Testimony of Thomas Deuschle, hearing of the Senate Committee on Commerce, Science and Transportation, March 4, 1997; Testimony of Dr. Steven Gunther, Chief Resident of Orthopaedics at George Washington University Hospital in Washington, D.C., hearing of the Senate Committee on Commerce, Science and Transportation, March 4, 1997.

Dr. Steven Gunther testified about his experience following an October 1996 incident in which he sustained second- and third-degree burns over sixty-five percent of his body. The severity and scope of his burns made the threat of infection and dehydration deadly possibilities. Shortly after Dr. Gunther sustained his injuries, his legs were wrapped in a new medical product known as Integra. Integra is a two layer “artificial skin” made from bovine collagen and silicone that prevents both infection and fluid and electrolyte loss. The Integra effectively “masked” the burns on his legs, allowing his physiological defense mechanisms to focus on those parts of his body that did not receive Integra. As a result, the healing process was hastened exponentially. Dr. Gunther has now resumed his Orthopaedic practice full-time. He strongly urged passage of federal biomaterials access assurance legislation.

Title II of the Act will safeguard the availability of a wide variety of lifesaving and life-enhancing medical devices. It would allow suppliers of the raw materials (biomaterials) and component parts used to make medical implants, to obtain dismissal, without extensive discovery or other legal costs, in certain tort suits in which plaintiffs allege harm from a finished medical implant. Suppliers are not generally liable under existing law in such situations, and the Act would not, as a practical matter, provide any broader immunity than suppliers already have. The point of Title II is not to change the standard of liability in any substantial way, but rather to protect suppliers from costly litigation that is today putting at risk the supply of vital raw materials and components to device manufacturers.

The Act would not apply to claims brought by any person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel. The Act also would not affect the ability of plaintiffs to sue manufacturers or sellers of medical implants.

THE SO-CALLED “FRAUDULENT SUPPLIER” MYTH SHOULD BE REJECTED

Some opponents of federal legislation have argued that the Act could somehow diminish the protections available under existing law to ensure that suppliers do not fraudulently misrepresent the safety of their raw materials and components for use in medical implants. It would not.

First, this Committee is not aware of a single reported case of a supplier being held liable to a medical implant recipient based on proof of fraud. Thus, the notion that the Act would provide “protections” against such conduct is simply a red-herring.

Second, in an appropriate case, a court could hold a supplier liable under Title II on the grounds that, as a result of its fraudulent misrepresentation, the raw materials or components did not constitute the product described in a contract with the manufacturer or violated specifications the supplier had published or had agreed to.

Third, the rigorous regulatory safeguards applicable to the manufacture of medical devices makes the likelihood of fraudulent conduct extremely remote, even in a “hypothetical world.” The FDA requires manufacturers to safety test raw materials and components used in devices and to have systems for ensuring that raw mate-

rials and components meet specifications set forth in contracts with suppliers. Accordingly, manufacturers are required to satisfy themselves and the FDA that the raw materials and components they use are safe. Because of these requirements, most common law courts today hold (albeit often after protracted discovery) that liability should be placed on the manufacturer, not the supplier, regardless of what the supplier knew or should have known about its product. In this regard, Title II changes only the procedures, but not the results, of cases arising under existing law.

Courts rarely hold suppliers liable if a raw material or component is properly manufactured and is inherently safe in most of its end uses, but becomes hazardous only as used in a particular type of finished product.²²⁰ Instead, under the bulk supplier or learned intermediary doctrine, the manufacturer of the finished product is usually held liable. Title II preserves this general allocation of liability.

Fourth, an additional protection against supplier wrongdoing is the ability of a medical device manufacturer to sue its supplier. Because Title II addresses the liability of suppliers to persons who claim to have been injured as a result of an implant that incorporates raw materials or components sold by those suppliers, it is not intended to restrict any rights other persons may have to sue suppliers under a variety of state law theories. The Title also would not affect the scope of a supplier's liability to such persons under state common law doctrines. As a result, an implant manufacturer may sue a supplier for breach of warranty or contract violations, if such claims exist under state law, without regard to the provisions of this Title.

Section 201—Short title

Section 201 states this title may be cited as the “Biomaterials Access Assurance Act of 1997.”

Section 202—Findings

Section 202 contains the “Findings” upon which this title is based.

Section 203—Definitions

Section 203 defines terms or phrases used in this title. Litigation concerning silicone gel breast implants is excluded from the Act. This result is accomplished through the definition of “claimant.” Section 203(2)(D)(iii) excludes from the definition of “claimant” any person “alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel.” As the statutory language makes clear, this exclusion was not based on a determination that silicone gel or any other form of silicone causes or may cause adverse health effects.

The Act specifically prohibits the exclusion from being used improperly to imply that Congress has made a finding regarding the

²²⁰See, e.g., *Kealoha v. E.I. du Pont de Nemours and Co., Inc.*, 82 F.3d 894 (9th Cir. 1996) (no liability for supplier of raw material used in jaw implants); *Crossfield v. Quality Control Equipment Co.*, 1 F.3d 701 (8th Cir. 1993) (no liability for supplier of chain used in cleaning machine); *Childress v. Gresen Manufacturing Co.*, 88 F.2d 45 (6th Cir. 1989) (no liability for supplier of valve used in log splitter).

health effect of silicone or silicone implants. Section 203(2)(D)(iii) specifically states that even the existence of this exclusion shall not be disclosed to a jury in any civil action or other proceeding. The same section also makes it clear that the exclusion shall not be presented in any type of proceeding except as necessary to establish the applicability of the Act. This would only happen in the unlikely event that a defendant in a breast implant case were to assert one of the defenses provided by the Act.

Section 204—General requirements; applicability; preemption

Section 204(a) specifies that, in any civil action covered by the title, a biomaterials supplier may raise any defense set forth in section 205, and the court must use the procedures set forth in section 206 in connection with that defense.

Section 204(b) states that the title applies to any civil action brought by a claimant in Federal or State court against a manufacturer, seller, or biomaterials supplier, on the basis of any legal theory, for harm allegedly caused by an implant.

Section 204(c) states that the title preempts State law to the extent the bill establishes a rule of law.

Section 204(d) also states that the title may not be construed to affect any defense available under other provisions of law to a defendant in an action alleging harm caused by an implant, or to create any new Federal cause of action.

Section 205—Liability of biomaterials suppliers

Section 205 restricts the possible liability of biomaterials suppliers in lawsuits covered by the title to three situations, where the supplier: (I) was itself the manufacturer of the implant; (ii) was itself the seller of the implant; or (iii) furnished raw materials that failed to meet applicable contractual requirements or specifications.

A supplier may be deemed to be a manufacturer only if the supplier registered as such with the FDA pursuant to medical device requirements or if the Secretary of HHS issues a declaration that the supplier should have registered as a manufacturer. Section 205 also establishes a procedure for the Secretary to issue such a declaration.

A supplier may be deemed to be a seller and thus liable in situations in which the supplier itself resold the implant after it had been manufactured and had entered the stream of commerce.

With respect to contractual requirements, a supplier may be liable for harm only if the claimant shows that the biomaterials were not the actual product for which the parties contracted or the biomaterials failed to meet certain specifications and that failure was the cause of the injury. The relevant specifications are those: (I) provided to the supplier by the manufacturer; (ii) provided by the manufacturer (either published, given to the manufacturer, or included in an FDA master file); or (iii) included in manufacturer submissions that had received clearance from the FDA.

Section 206—Procedures for dismissal of civil actions against biomaterials suppliers

Section 206(a) establishes a new procedure for dismissal of lawsuits against suppliers. A supplier named as a defendant or joined

as a co-defendant may file a motion for dismissal based on the defenses set forth in section 205.

Section 206(b) specifies additional procedural requirements for the lawsuits against suppliers. A plaintiff must sue a manufacturer directly whenever jurisdiction over the manufacturer is available.

Section 206(c) establishes procedural requirements for the proceeding on a motion to dismiss. Pretrial discovery is limited to certain issues and to the scope permitted against third parties. A motion on the ground that the supplier is not a manufacturer would be automatically granted if the supplier had not filed with the FDA as a manufacturer of the implant unless the plaintiff obtained a ruling from the FDA that the supplier should have registered as a manufacturer. A ruling on the supplier's pretrial motion for dismissal is based solely on the pleadings and any affidavits.

Under section 206(d) the court may treat the motion for dismissal as a motion for summary judgment if the pleadings and affidavits raise genuine issues of material facts with respect to a motion concerning compliance with contractual requirements and specifications. Discovery is limited to establishing whether an issue of material fact exists. The court would grant the summary judgment motion unless the plaintiff has submitted evidence sufficient to allow a jury to reach a verdict for the plaintiff.

Section 206(e) provides that, if a plaintiff has filed a petition with the FDA to obtain a ruling from the FDA that the supplier should have registered as a manufacturer, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition.

Section 206(f) and (g) change other procedural aspects to reduce litigation burdens. The manufacturer, not the supplier, may conduct the proceeding on the motion if an appropriate contractual indemnification agreement exists. The possibility of frivolous claims against a supplier is reduced by permitting the court to require the plaintiff to pay attorney fees if the plaintiff succeeds in making the supplier a defendant, but ultimately is found to have a meritless and frivolous claim.

TITLE III—LIMITATIONS ON APPLICABILITY; EFFECTIVE DATE

Section 301—Effect of Court of Appeals decisions

Section 301 provides that a decision by a Federal circuit court of appeals interpreting a provision of this Act (except to the extent that the decision is overruled or otherwise modified by the United States Supreme Court) shall be considered a controlling precedent with respect to any subsequent decision made concerning the interpretation of such provision by any Federal or State court within the geographical boundaries of the area under the jurisdiction of the circuit court of appeals.

Section 302—Federal cause of action precluded

Section 302 indicates that the Act does not provide any new basis for federal court jurisdiction. The resolution of claims subject to

this Act is left to state courts or to federal courts that currently have jurisdiction over those claims.

Section 303—Effective date

Section 303 provides that the Act governs any civil action subject to the Act that is commenced on or after the date of enactment, without regard to whether the harm that is the subject of the action or the conduct that caused the harm occurred before the date of enactment. The Act does not apply to actions filed before the date of enactment, but litigated after enactment. As the Act does not apply to such actions, the Act also does not apply to actions remanded or appealed after the date of enactment, but commenced before that date.

ROLLCALL VOTES IN COMMITTEE

At the close of debate on S. 648, the Chairman announced a rollcall vote on the bill. On a rollcall vote of 11 yeas and 9 nays as follows, the bill was ordered reported without amendment:

YEAS—11	NAYS—9
Mr. McCain	Mr. Hollings
Mr. Stevens	Mr. Inouye ¹
Mr. Burns	Mr. Ford
Mr. Gorton	Mr. Rockefeller
Mr. Lott	Mr. Kerry ¹
Mrs. Hutchison	Mr. Breaux
Ms. Snowe	Mr. Bryan ¹
Mr. Ashcroft	Mr. Dorgan
Mr. Frist ¹	Mr. Wyden
Mr. Abraham	
Mr. Brownback ¹	

¹By proxy

MINORITY VIEWS OF MR. HOLLINGS

INTRODUCTION

The reporting of this bill marks the fifth consecutive Congress in which this Committee has reported legislation to federalize our nation's product liability system. Fortunately, good-will has prevailed upon members of Congress and prevented such measures from becoming law.

It is well known that I have opposed the passage of federal product liability legislation. Philosophically, I believe that this is an area of law that is best reserved to the states. I am convinced that state and local governments have a better idea of what is good for the health and safety of their citizens than the United States Congress.

As I have stated in the past, those who propose such dramatic change should, at a minimum, be required to prove that such change is warranted, and likely to be effective. The proponents, however, have had fifteen years to make their case and have failed to do so. Every argument that has ever been made in support of this legislation, from the so-called litigation explosion to competitiveness, has been totally refuted by the data. Unfortunately, the

Committee again has ordered the legislation reported without such proof. This is not sound policy-making nor credible action by this Committee.

The primary argument in support of the legislation is that it is needed because of the excessive litigiousness of American citizens. Such behavior reportedly has been stirred by massive jury awards, which has precipitated an on-going litigation crisis. The so-called litigation crisis allegedly has reduced the availability of liability insurance, as well as hindered the competitiveness of American businesses. Proponents claim that by preempting state law, and imposing national standards, the bill will make the liability system more fair and efficient for both consumers and businesses.

These arguments have been thoroughly reviewed and analyzed by a number of well respected independent organizations over the past decade. They include the Rand Institute for Civil Justice, the General Accounting Office (GAO), the Insurance Information Institute, the National Association of Insurance Commissioners, the National Center for State Courts, the American Bar Association, and a number of independent legal experts.

The common conclusion of the work done by each of these groups is that (1) to the extent there was an insurance crisis, it was not due to the product liability system, but primarily was caused by the underwriting practices of insurance companies; (2) the product liability system has no impact on, and is not stifling, American business competitiveness; (3) products kept off the market because of product liability concerns are not necessarily safe or innovative, but rather are examples of the system working properly to deter potentially dangerous products; and that (4) Americans are not overly-litigious, nor are product liability lawsuits out of control or burdening the courts.

Specifically, the proponents claim that the legislation is needed to make insurance more available and affordable, particularly for small businesses. Volumes of evidence have been presented, however, demonstrating that these insurance problems are not, and were not, due to product liability. To the extent there was an insurance crisis, it was caused by insurance companies' underwriting practices, not the product liability system. During the late 1970s, insurance companies attempted to market low-premium products to expand market share, while generating investment income. When the market declined, and investment rates didn't positively correspond, companies raised premiums to cover potential losses. Instead of acknowledging that premium increases were necessitated because of their underwriting practices, however, the industry targeted and blamed the product liability system. This marked the beginning of the mythical litigation crisis, which has become the basis for this legislation. The litigation myth has been recognized by a number of respected organizations, including the Risk and Insurance Management Society (RIMS), which is comprised of some of the largest industrial corporations in the country. During the mid-eighties, the organization expressed serious concern about linking tort reform legislation and the insurance availability crisis.

Even if the bill is passed, however, the insurance industry has testified before the Committee that such measures will have virtually no effect on insurance costs. Realistically, the only way to

determine the impact of claims, or any legislation, on insurance rates is through the collection of objective data on insurance costs. I have offered, on several occasions, legislation to require the collection of data for such purposes. These measures have been strongly supported by small businesses. The supporters of S. 648, however, have strongly opposed insurance data collection. I truly question the intent of the bill if it is not designed to reduce insurance costs (which is the bulk of litigation expenses for most businesses), and how there will be an actual understanding of the legislation without the proper data.

The proponents' assertion that product liability is hindering the competitiveness of American businesses also is without merit, and has been unequivocally refuted by numerous studies and surveys. A recent survey by RIMS revealed that liability insurance costs for most businesses are less than 1% of total revenues. A Conference Board survey of risk managers of 232 corporations shows that product liability costs for most businesses are 1% or less of the final price of a product, and have very little impact on larger economic issues, such as market share or jobs. A Rand Corporation study found that less than 1% of U.S. manufacturers are ever named in a product liability lawsuit, and concluded that "available evidence does not support the notion that product liability is crippling American business." The General Accounting Office (GAO) recently stated that it could find "no acceptable methodology for relating product liability to competitiveness," and that businesses refuse to release the information needed to conduct such an analysis.

As part of their competitiveness arguments, the bill's supporters contend the liability system is impeding the introduction of potentially life-saving drugs and medical products by the drug and medical device companies. However, according to testimony from drug companies themselves, the United States is the world leader in developing new medicines, and that U.S. companies have been responsible for about half of the new patented drugs that have reached the global market since 1970. A recent report by Fortune magazine rated the American pharmaceutical industry the number one industry in the United States with respect to competitiveness. These reports make clear that if the product liability system is impeding the competitiveness and the introduction of new products by the U.S. drug industry, it certainly is not evident in the industry's market performance.

The supporters of the bill also claim that foreign businesses have an advantage over American businesses because of the more restrictive civil rules in other countries. However, what the bill's supporters fail to recognize is that the American judicial system is premised upon a democratic structure, whereby the people, as jurors, resolve conflicts. The American jury system, indeed, differs from the judicial system of other countries that are predicated upon elite structures such as permitting singularly appointed judges to resolve conflicts rather than juries. There is no justification for compromising this cherished liberty in our country.

Additionally, if it is true that foreign businesses have an advantage over American businesses, such disparities will not be alleviated by this bill. Because the legislation makes no distinction be-

tween foreign and American businesses, whatever advantages foreign businesses have because of the structure of their governments will remain. The only result will be that foreign businesses will be able to take advantage of their home-country legal restrictions, as well as the legal limitations that will be imposed on American citizens. The big loser is the American consumer.

The proponents' assertion that there is a litigation explosion and that Americans are overly litigious is also a false argument. A recent Rand Corporation study found that only 1 out of every 10 Americans that are injured due to product hazards ever seeks compensation through the tort system. Of these cases, two-thirds involve motor vehicle accidents, not product liability suits. The study concluded that Americans' behavior does not accord with the more extreme characterizations that some have put forward of an overly litigious society. In fact, a study by Professor Marc Galanter of the University of Wisconsin Law School has found that the real increases in litigation in recent years have involved businesses suing each other for multi-million dollar claims, not injured persons seeking redress of their rights. Nevertheless, the legislation has been written to ensure that business suits are not affected by the restrictions in the bill.

The proponents will cite statistics which indicate that there were increases in product liability claims during the 1980s. However, what they fail to acknowledge is that a majority of these product liability filings involved highly dangerous products. Those products included asbestos, the Dalkon Shield, and the Copper 7 IUD. Suits against asbestos manufacturers revealed that the manufacturers knew that the substance was cancerous, but made a profit motive decision to withhold the information from the public. Cases involving the Dalkon Shield, an intrauterine device for birth control, revealed that the manufacturer knew the device could cause women to suffer life-threatening spontaneous abortions, but made no attempt to warn users of such dangers. One judge called the device "a ticking time bomb in women's wombs." In a case involving the Copper 7 IUD, the court concluded that the plaintiff presented evidence to show that the company "knowingly placed millions of American women, especially [women who have not had children], at risk of serious infection, loss of fertility, and surgery for the removal of internal organs." Each of these manufacturers was forced to withdraw their products from the market, which is one of the purposes of the product liability system. Yet, proponents are still imposing restrictions on the system that would, in effect, make it more difficult to sue individuals who engage in such conduct.

While these attempts at justification for the bill are groundless, I am equally concerned about various specific provisions in the bill that adversely will impact consumers. Proponents of the legislation have described the bill as one that is designed to achieve fairness and balance. However, they are as inconsistent in their claims about the intent and impact of the legislation as they are in their arguments justifying the need for the bill.

Proponents claim the bill is needed to make the judicial system more fair and efficient, and more responsive to injured consumers. These objectives, however, certainly are not evident in the legislation. For example, proponents argue that the legislation is designed

to establish uniform rules. However, the bill, in most instances, only selectively preempts state law. This selective preemption is designed to ensure that state laws are preempted only to the extent the law does not comport with the interest of the business community.

The punitive damages section clearly illustrates this inconsistency. The bill purports to establish national standards on punitive damages. Yet, the legislation would preempt state law only if the state permitted the assessment of punitive damages. Thus, states that do not permit punitive awards would not have their law disturbed. This clearly will not result in a uniform system of punitive damages. Since manufacturers and sellers would rather not be subjected to punitive damages at all, the bill is designed in a way to accommodate that interest. This political maneuvering, however, makes the bill one-sided, and non-uniform.

The bill also fails to meet the proponents' fairness claims. This contradiction also is demonstrated in the punitive damages section. First, the legislation contains arbitrary caps on punitive damages. It is unclear why such caps are necessary since punitive damages are rarely awarded in product liability cases. Second, as applied, the bill would discriminate based on income. The legislation provides that punitive damages are to be capped at two times economic and non-economic damages or \$250,000, whichever is greater. By basing the cap on economic damages (income and wealth), the bill will create a law that will allow for higher punitive awards in cases involving harm to wealthy citizens. The obvious message of such law is that the greater a plaintiff's wealth, the more a company should be punished. The bill's supporters have argued that since the formula also is linked to pain and suffering damages, the disparities based on wealth will be alleviated. I do not discern the validity of this argument, since one would presume that rich and poor citizens will incur the same amount of pain and suffering.

A provision has been incorporated into the bill to allow judges to increase awards beyond the cap (an authority not given to juries), if the judges determine the cap to be insufficient. This provision purportedly is designed to reduce the unfairness of the punitive damages section. Judges in most jurisdictions, however, are constitutionally prohibited from increasing awards independently of juries, and without the consent of the parties. Thus, if the legislation becomes law, the likely scenario is that the authority granted to judges will be deemed unconstitutional, leaving the arbitrary cap in tact. Furthermore, it is questionable why Congress would propose a law it recognizes as unfair, and then shift the responsibility to judges to rectify the problem. If the provision is bad policy, it should never be proposed by this body. It also is questionable as to why Congress would engage itself in such intimate and minute legal issues, such as the determination of damages, in a field of law in which it has no experience in regulating.

Moreover, the proposed caps will undermine the real intent of punitive damages—which is to hold out the possibility that an individual will face extreme punishment, so as to deter egregious and willful conduct. Numerous cases have shown the significant role punitive damages, and the threat of litigation, have played in forcing the removal of highly dangerous products from the market.

Only after a \$10 million punitive damage award against Playtex did that company remove from the market tampons linked to Toxic Shock Syndrome in 1988. The 10th Circuit Court of Appeals found that "Playtex deliberately disregarded studies and medical reports linking high-absorbency tampon fibers with increased risk of toxic shock." Notwithstanding such conduct, if S. 648 had been the law at that time, the company's punitive damages would potentially have been limited to \$250,000 in cases involving working-class and low-income women. Does it really make sense that such a small penalty would have sent a serious message to this company?

It is perplexing why proponents are seeking to protect individuals who engage in such conduct by limiting the amount of punitive damages that can be assessed against them. It is not surprising that so many Americans are wondering what is happening in Washington.

The proponents argue that the two-way preemption provision in the 18-year statute of repose section is evidence of the bill's consumer benefits. By preempting states that have statutes providing for shorter periods of repose, the bill allegedly will provide consumers in those states a more favorable period for seeking compensation through the tort system.

According to the Congressional Research Service (CRS), however, the legislation will have the opposite effect. CRS' research shows the bill actually would reduce rights currently available to consumers in over 30 states. Additionally, the provision is severely more stringent than provisions in previous product liability reform bills. In past bills, the statute of repose was limited to work-place products. S. 648, however, applies to all consumer products. They include home appliances, such as furnaces and garage doors, as well as devices subject to common usage by the public, such as elevators and recreational equipment. Persons injured by such devices would be completely barred from suing if the device was more than eighteen years old. This bar would apply even if there is evidence that the manufacturer, seller, or business knew the device was dangerous and defective.

Moreover, it is interesting that the statute of repose two-way preemption provision is being touted as evidence of the bill's pro-consumer benefits, since the other provisions, such as the punitive damages and joint and several liability sections, do not contain two-way preemption provisions. Supporters of the bill have gone through great strides of ensuring that they do not create any cause of action whatsoever for such damages. Thus, consumers in jurisdictions without punitive damages will not receive the benefit of the protections punitives provide; however, consumers in states that allow for punitive damages will have the deterrence factor of such damages diminished by arbitrary caps.

The proponents are proposing to completely bar suits against suppliers of biomaterials and component parts that are used in medical devices. This bar would apply even if there is evidence that the substance or device caused the harm and the suppliers knew of such dangers. This is one of the issues the President highlighted in his veto message of last year. There is absolutely no basis for this wholesale exemption, since there is no evidence that the medi-

cal device industry or suppliers are burdened by product liability lawsuits.

The legislation eliminates joint liability for damages for pain and suffering (non-economic damages). Joint liability simply means that all persons involved in distributing and profiting from a dangerous or defective product, and who have engaged in irresponsible behavior that led to the plaintiff's injury caused by the product, are to be held liable for the plaintiff's harm. The social policy behind this doctrine is that all defendants involved in profiting from the product, and from distributing the product in the stream of commerce, should bear the responsibility for the defects and dangers associated with the product, not the injured person. Instead of holding all responsible, however, S. 648 proposes to divide negligent defendants' responsibilities into arbitrary percentages—e.g., 5% at fault or 10% at fault.

The provision also on its face is inherently contradictory. It retains joint and several liability for economic damages (medical bills) but eliminates it for pain and suffering damages. This suggests that the bill's supporters are willing to hold all parties responsible to make sure plaintiffs' bills are paid, but are not willing to hold all negligent parties responsible to ensure plaintiffs are securely compensated for the actual damages due to them for their pain and suffering.

These are just a few examples of the dangerous portent of this bill to consumers, as well as the contradictions in the supporters' arguments about the need for and intent of the legislation. Clearly, we should not misunderstand the purpose of this legislation. It is written for the benefit of the business community, not for consumers or to make the system more uniform. The danger posed by this legislation is demonstrated by the groups opposed to its passage. These organizations include over 100 consumer and health groups. They include the Consumer Federation of America, Public Citizen, Consumers Union, the American Public Health Association, and the Women's Legal Defense Fund. They all have warned about the dire consequences the bill will have on American consumers.

As I have stated in the past, if there are issues that need to be examined in the tort system, they already are being addressed by the states, where this issue belongs. Since 1983, 46 states have enacted measures involving tort reform. The states—through their work with members of the bar, chambers of commerce, the insurance industry, and consumer groups—have addressed concerns about the tort system, and have crafted legislation they believe is in the best interest of their citizens. The proponents of S. 648, however, would override the enormous and commendable effort and time the states have devoted to this issue, and force their own brand of reform on the states.

I yield to no one in my desire to assist American businesses in every way possible. However, I urge my colleagues to insist, at a minimum, on some objective demonstration that federal product liability law is a reasonable means to address the problems of the business community. The evidence is clear that if the majority of Committee members were really concerned about U.S. business competitiveness and creating jobs, the Committee would be addressing more serious and relevant issues that really affect busi-

nesses. This Committee has jurisdiction over a wide range of important economic issues, such as trade, international antitrust, insurance regulation, and competition in the market place. It would well serve the Committee, the American public, and the business community, if more time were dedicated to these matters, instead of measures like this legislation.

In the discussion below, I have set out in more detail the facts that have been developed on this issue, and why I believe we should not move forward on this bill.

THERE IS NO FACTUAL BASIS FOR THIS LEGISLATION

I. THE CURRENT SYSTEM ACHIEVES FAIR RESULTS, AND THERE IS NO "EXPLOSION" OF LITIGATION

Before we make dramatic changes in product liability law, we should, at the least, have information to demonstrate that the current system needs fixing. It is not achieving its purpose of fairly and properly compensating victims of defective products, or of deterring the marketing of unsafe products. As each additional piece of objective data becomes available, it becomes more clear that the system is working. The number of non-asbestos product liability cases is actually declining, punitive damages are a rare occurrence, and compensatory awards are reasonably related to the cost of the injuries involved.

In 1991, the Rand Corporation released a report on civil claims and compensation, which found that only 10% of persons that are injured by defective products seek some form of compensation through the tort system. A mere 2% actually goes forward with filing a lawsuit.¹ The report further found that only 7 percent of all compensation for accident victims is paid through the tort system.² This low level of compensation is obviously due to the reluctance of injured persons to file claims or lawsuits. The report concluded that "most Americans who are injured in accidents do not turn to the liability system for compensation. . . . In this respect, Americans' behavior does not accord with the more extreme characterizations of litigiousness that have been put forward by some."³

The most recent statistics from the National Center for State Courts on state civil filings show that product liability cases constitute only 4% of all state tort filings, and a mere 36 hundredths of one percent (.0036) of all civil cases.⁴

Jury Verdicts, Inc., has found in its recent studies that juries nationwide have become much tougher on plaintiffs.⁵ The report revealed that a plaintiff's chances of winning in tort cases decreased from 65% to 42% between 1987 and 1992, and among product liability cases specifically, the percentage of favorable verdicts for plaintiffs fell from 59% to 41% between 1989 and 1993.⁶ The report

¹Hensler, et al., "Compensation for Accidental Injuries in the United States," Rand Corporation, Institute for Civil Justice (1991), Executive Summary at 18. See also testimony of Dr. Deborah Hensler, Consumer Subcommittee Hearing on S. 640, September 12, 1991, statement at 6.

²Id.

³Id., Executive Summary at 18, 20.

⁴National Center for State Courts, "State Court Caseload Statistics: Annual Report 1989," (February 1991) at 46. State Court Caseload Statistics, supra n. 5, at 45-6.

⁵New York Times, Friday, June 17, 1994.

⁶Id.

also indicated that there have been major declines in the number of cases filed and the size of awards.⁷

In 1992, Professors James Henderson—a supporter of tort reform—and Theodore Eisenberg of Cornell University released a study, “Inside The Quiet Revolution In Products Liability,” which also found notable declines in the number of product liability cases filed, as well as significant decreases in the size of awards.⁸ The study concluded that by most measures, product liability has returned to where it was at the beginning of the decade. The study confirmed Professors Henderson’s and Eisenberg’s findings in an earlier study, which found a “quiet revolution . . . away from extending the boundaries of products liability and toward placing significant limitations on plaintiffs’ rights to recover in tort for product-related injuries.”⁹ Specifically, they found that in 1976 and continuing to 1983, defendants benefitted in roughly 51 percent of product liability cases. By 1988, defendants prevailed in 63.4 percent of product liability cases. The study concluded that, even if product liability cases could be characterized as unfairly favoring plaintiffs in the past, the current trend is clearly favoring defendants.

The GAO in 1989 completed one of the first extensive reviews of data related to state court product liability cases.¹⁰ Since most product liability cases are litigated in state court, and most of the past data has been only from the federal courts, this report is very significant. GAO found that the size of compensatory awards varied by type and severity of injury in a manner consistent with underlying economic loss, so that compensatory awards were neither erratic nor excessive.¹¹ It further found that plaintiffs won fewer than 50 percent of the cases litigated, that awards were based on negligence in almost three-quarters of the cases (even in the states that permit recovery based on strict liability without a demonstration of negligence), and that the amount of punitive damages awarded was highly correlated with the size of compensatory damages.¹²

Additionally, in testimony submitted to the Committee in September of 1991, Professor Marc Galanter of the University of Wisconsin Law School stated that, if asbestos cases are excluded, the number of product liability cases in the federal courts has declined in the last 5 years—from 8,268 cases in 1985 to 4,992 in 1991, a 40 percent decrease.¹³ He indicated that asbestos filings accounted for all the increases in product liability filings in the 1980s, and that asbestos cases are quite distinct in that they involve a product of “unparalleled deadliness to which there was massive exposure

⁷Id.

⁸Henderson and Eisenberg, “Inside the Quiet Revolution In Products Liability,” 39 U.C.L.A. Law Review 731, 743 (1992).

⁹Henderson and Eisenberg, “The Quiet Revolution in Products Liability: An Empirical Study of Legal Change,” 37 U.C.L.A. Law Review 479, 480 (1990).

¹⁰U.S. General Accounting Office, “Product Liability: Verdicts and Case Resolution in five States,” GAO/HRD-89-99 (September 1989). Hereafter referred to as “1989 GAO Report.”

¹¹Id. at 27.

¹²Id. at 29-31.

¹³Testimony of Professor Marc Galanter, Director, Institute of Legal Studies, University of Wisconsin Law School, before the Consumer Subcommittee September 19, 1991, transcript at 86-87. See also Galanter and Rogers, “A Transformation of American Business Disputing? Some Preliminary Observations,” working paper #DPRP 10-3, Institute for Legal Studies, University of Wisconsin (April 1991).

that continued long after the dangers of its use were suspected and suppressed.”¹⁴

Professor Galanter’s findings are similar to reports of federal civil filings by the GAO¹⁵ and the Rand Corporation¹⁶, which have shown that one product, asbestos, accounted for approximately 60 percent of the growth in filings between 1976 and 1986.¹⁷ GAO further found that, since 1981, product liability cases have grown at about the same rate as other civil filings and at the same rate as personal expenditures on goods, with growth of product liability cases at 4 percent, personal expenditures on goods at 4 percent, and civil filings at 6 percent.¹⁸ The author of the Rand study has stated that “[m]y feeling is that the available evidence doesn’t support the notion that products liability is crippling American business.”¹⁹

II. THE REAL LITIGATION EXPLOSION

According to Professor Galanter, the real increase in litigation in recent years has been in businesses suing businesses, not consumers seeking compensation through the product liability system.²⁰ For example, contract filings in federal courts increased by 232 percent between 1960 and 1988, and by 1988 were the largest category of civil cases in the federal courts.²¹ Statistics compiled from the National Law Journal’s annual reports on major civil verdicts show that, since 1989, 73% of the largest civil verdicts in the nation have involved business litigation, not product liability cases.²² Between 1987 and 1994, just 76 of the largest verdicts alone accounted for more than \$10 billion.²³ Statistics from the National Center for State Courts show that at least several hundred thousand business and contract cases were pending during this period.²⁴

The Harvard Business Review recently featured a report on corporate litigation and Alternative Dispute Resolutions (ADR) which provided an insightful view on the litigious behavior of businesses. Although ADRs are designed to avoid litigation and save costs, such hopes have faded for businesses as a result of legal billings, high damage awards, and the propensity of businesses to litigate.²⁵ The report indicated that ADRs have become for businesses a disguise for litigation, sometimes costing more than a normal court proceeding.²⁶ In addition, businesses often prefer litigation to ADR. A survey found that few senior corporate managers are willing to forgo a chance to win a courtroom triumph. A top lawyer of a major company stated that “CEOs want to be able to take the other guy to the cleaners if they believe that they’re in the right, and are

¹⁴ Galanter testimony, *supra*, transcript at 88.

¹⁵ U.S. General Accounting Office, “Product Liability: Extent of ‘Litigation Explosion’ in Federal Courts Questioned,” GAO/HRD-88-36BR (January 1988).

¹⁶ Dugworth, “Product Liability and the Business Sector: Litigation Trends in Federal Courts,” Rand Corporation, The Institute for Civil Justice, R-3668-ICJ (1988).

¹⁷ GAO Report, *supra*, note 12, at 32, 43.

¹⁸ *Id.* at 32, 43.

¹⁹ Wall Street Journal, “Survey Questions Liability Crisis at U.S. Companies,” January 18, 1989.

²⁰ *Supra* at 13.

²¹ *Id.*

²² See National Law Journal Annual Reports on Largest Civil Verdicts (1990-1994).

²³ *Id.*

²⁴ *Supra* at 4.

²⁵ Harvard Business Review (May-June 1994) at 120.

²⁶ *Id.*

going to bet the ranch if they have to.”²⁷ Yet the proponents do nothing in the legislation to address the problems associated with business litigation. In fact, they have purposely exempted business suits from the bill.

III. JURIES RARELY AWARD PUNITIVE DAMAGES

Much has been made of the unpredictability of results in product liability trials. However, it has been recognized, as it must be, that most of this is due to our jury system. I cannot believe any of my colleagues want to tamper with that system. When a product liability case goes to trial, the jury is not impaneled for the purpose of giving away someone else's money. Rather it is charged with the administration of justice. These juries are composed of our friends and neighbors, who conclude, some of the time, that the defective products involved and the injuries sustained require compensation. And it is our friends and neighbors—who work for a living and know the value of a dollar—who occasionally conclude that punitive damages are justified when the defendant has engaged in outrageous behavior. Moreover, these are the same citizens who vote to elect members of Congress. Why is it that they can be charged with the important responsibility of electing members of this body, but lack the ability to resolve disputes in product liability cases?

If there is an issue that has been terribly exaggerated in this debate, it is the issue of punitive damages. Much new data is available on punitive damages, which show, among other things, that very few punitive damage awards have been made in all state and federal product liability cases over the last 25 years. Punitive damages simply are not a factor in any but the rare product liability case, and have little effect on the business community. Dr. Stephen Daniels of the American Bar Foundation conducted a nationwide study of over 25,000 civil jury awards between 1981 and 1985. The study found that punitive damages were awarded in only 4.9% of the cases reviewed.²⁸ He stated that the debate over punitive damages “changed in the 1980s as a part of an intense, well-organized, and well-financed political campaign by interest groups seeking fundamental reforms in the civil justice system benefiting themselves.” He went on to state that this “politicization of the punitive damages debate . . . makes the debate more emotional and manipulative, and less reasoned. The reformers appeal to emotions, fear, and anxiety in this political effort while avoiding reason and rational discourse.”²⁹

He concluded that punitive damages were not routinely awarded, were awarded typically in modest amounts, and were awarded more often in financial and property harm cases [business v. business] than in product liability cases.³⁰ His research also pointed up the errors in the data from Cook County, IL, and San Francisco, CA, which in the past have been cited by supporters of bills like S. 648 as indicative of the nationwide pattern on punitive damages.

²⁷Id. at 123.

²⁸Daniels and Martin, “Myth and Reality in Punitive Damages,” 75 Minn. Law Review 1, 10–12 (Oct. 1990).

²⁹Testimony of Dr. Stephen Daniels, Consumer Subcommittee Hearing on S. 640, September 12, 1991, transcript at 122.

³⁰74 Minn. L.Rev., supra, at 43.

He found that there were flaws in the method of data analysis used, and that it was inappropriate in any event to generalize from data in two counties to a nationwide trend.³¹

On April 4, 1995, Dr. Daniels, testifying before the Committee, submitted data on a study he conducted to review his initial findings. Using the same database in a review of the same sites for years 1988–1990, he found that punitive damages were again awarded at an extremely low rate—4.8%.³² The study confirmed his earlier findings that such awards are more of an aberration than the norm.

Dr. Daniels' findings are similar to those by Professor Michael Rustad of Suffolk University Law School and Professor Thomas Koenig of Northeastern University. The Supreme Court recently referred to this report as "the most exhaustive study of punitive damages". Professors Rustad and Koenig reviewed all product liability awards from 1965 to 1990 in both state and federal courts. During that time, punitive damages were awarded in only 355 cases—only 355 total punitive damages awards in 25 years! One quarter of all those awards involved one product—asbestos. Another one quarter of those cases was reversed or remanded upon appeal. They further found that the amount of punitive damage awards was not skyrocketing, and in 35 percent of the cases in which punitive damages were awarded they were less than the amount of compensatory damages. They concluded that "[t]here is a widespread misperception that punitive damage awards are skyrocketing because of frivolous lawsuits" ³³

By reviewing the data representative of the entire system, as opposed to the few anecdotes of high damage awards often cited by the supporters of this bill, we see that the system is not out of control in terms of numbers of cases filed or amount of compensation awarded. It also is important to note the beneficial aspects of the current system that stand to be undermined if this bill is enacted, as discussed below.

As indicated by testimony at the Committee's September 23, 1993 hearing, if a manufacturer is not engaged in flagrant disregard of safety, pursuant to the standard set under section 108 of the bill, then that manufacturer does not have to be concerned about punitive damages.³⁴ The possibility of punitive damages provides an important deterrent which helps to insure that manufacturers police themselves. We must require continued maximum vigilance from the manufacturers themselves. In its recent decision in *TXO Production v. Alliance Resources* (June 25, 1993, No. 92–479), the Supreme Court soundly rejected attempts to limit or abolish punitive damages.

³¹Id. at 22–27.

³²See testimony of Dr. Stephen Daniels, Consumer Affairs, Foreign Commerce and Tourism Subcommittee Hearing on S. 565, April 4, 1995.

³³Rustad and Koenig, "Demystifying the Functions of Punitive Damages in Products Liability: An Empirical Study of a Quarter Century of Verdicts," Executive Summary at 11–15, 1. See also testimony of Professor Michael Rustad, Consumer Subcommittee Hearing on S. 640, September 19, 1991, transcript at 74–78.

³⁴See Testimony of Lucinda Finley, Consumer Affairs, Foreign Commerce and Tourism Subcommittee Hearing, April 4, 1995.

IV. PUNITIVE DAMAGES CASES THAT MADE A DIFFERENCE

There is ample evidence demonstrating the benefits the product liability system and the threat of punitive damage awards have had in the removal of dangerous products from the market and potentially saving thousands of lives. The following are a few examples:

In 1980, a manufacturer of highly flammable pajamas stopped making the garment only after a \$1 million punitive damages award for the severe burns caused to a 4-year-old girl when her pajama top caught on fire. She suffered 2nd and 3rd degree burns over her upper body. Her scars are permanent, and she has suffered through several skin graft procedures. The company was well aware of the garment's flammability, as several other claims had been filed for similar injuries. The court quoted one company official as saying that the company was "always sitting on a power keg," even though treating the pajamas with flame-retardant chemicals was economically feasible. *Gryc v. Dayton Hudson Corp.*, 297 N.W.2d 727 (Minn. 1980), cert. denied, 101 S. Ct. 320 (1980).

*Only after a \$10 million punitive damage award against Playtex did the company remove from the market tampons linked to Toxic Shock Syndrome in 1988. In this case, Betty O'Gilvie died from Toxic Shock Syndrome after using Playtex's super-absorbent tampons. The 10th Circuit Court of Appeals found that "Playtex deliberately disregarded studies and medical reports linking high-absorbency tampon fibers with increased risk of toxic shock at a time when other manufacturers were responding to this information by modifying or withdrawing their high-absorbency tampons." *O'Gilvie v. International Playtex, Inc.*, 609 F. Supp. 817 (D. Kan. 1985), rev'd, 821 F.2d 1438 (10th Cir. 1987), cert. denied, 108 S.Ct. 2014 (1988).

*In this case, it took the Ford Motor Company two verdicts before it decided to address the "illusory park" defect in its automobiles. This defect in car transmissions manufactured between 1970 and 1979 gave the operator the impression that the car was secured when it was not. Vibration or slamming of car door could cause the automobile to move in reverse. About 90 injuries were reported as a result of this defect. A 1973 Lincoln suddenly moved backwards and ran over a woman's legs as she was unloading groceries. A jury found the transmission design was defective and that Ford had failed to properly warn consumers of the problem. It awarded compensatory damages and assessed \$4 million in punitive damages. A few months later, Ford eliminated the "illusory park" position hazard. *Ford Motor Co. v. Bartholomew*, 297 S.E. 2d 675 (Va. 1982); *Ford Motor Co. v. Nowak*, 638 S.W.2d 582 (Tex. App. 1982).

V. THE CURRENT SYSTEM PROMOTES PRODUCT SAFETY

One of the primary effects of the current system is to promote product safety—to make manufacturers more careful in the design and production of their products. In a 1987 Conference Board survey, risk managers of some of the nation's largest corporations stated that "[w]here product liability has had a notable impact—where it has most significantly affected management decision making—

has been in the quality of the products themselves.” Managers say products have become safer, manufacturing procedures have been improved, and labels and use instructions have become more explicit.³⁵

The increasing number of product safety managers inside corporations also is evidence of the impact the system is having on safety. According to the Consumer Federation of America (CFA), only a small minority of companies had a product safety management position in the early 1970s. By the end of the 1970s, virtually all companies had a very strong product safety presence in their management structure. CFA also has found that there has been a dramatic change in the rate of accidental injuries and deaths in the United States, so that “approximately 6,000 deaths and millions of injuries have been prevented on an annual basis now because of product liability and other forces towards greater safety in our society.”³⁶

Moreover, Professor Rustad in his survey of punitive damage awards found that 190 of the 252 non-asbestos defendants who were subject to punitive damage awards between 1969 and 1990 “have taken some safety step in the wake of punitive damages litigation. In eighty percent of these cases, there were steps such as fortified warnings, product withdrawals, and safety features added to products which followed shortly after the [litigation].”³⁷

A similar finding was made by Professors Nicholas Ashford and Robert Stone of MIT, in work done for inclusion in “The Liability Maze,” a collection of articles on product liability, innovation, and safety.

Professors Ashford and Stone researched the effect of product liability on the chemical industry. They found that manufacturers pay “no more than 5 percent, and often less than 0.1 percent, of the corresponding social costs” of the chronic injuries caused by chemicals.³⁸ They concluded that, although the system is not stringent enough on the manufacturers to provide appropriate deterrence to prevent all unsafe products, it still has helped in the development of safer products. They recommend, however, that if the liability system were more, not less, stringent with respect to manufacturers it would be even more effective in promoting safety and innovation.³⁹

The editor of “The Liability Maze,” Peter Huber, has suggested that the work by Professors Ashford and Stone is somehow unique. However, Professor Ashford has responded that he and other authors of the book found it impossible to separate innovation and safety, and found that “the liability system can both promote safety and innovation of desirable products and discourage unsafe products though they may be innovative.” Professor Ashford goes on to

³⁵“Product Liability: The Corporate Response,” The Conference Board Report No. 893 (1987) at 2.

³⁶Testimony of Gene Kimmelman, Legislative Director, Consumer Federation of America, at Consumer Subcommittee Hearing on S. 1400, April 5, 1990, transcript at 77–78.

³⁷Rustad, *supra*, executive summary at 28.

³⁸Ashford and Stone, “Liability, Innovation, and Safety in the Chemical Industry,” in *The Liability Maze* (Brookings 1991) at 414.

³⁹*Id.* at 415–417.

state that “we believe most scholars would subscribe to our methodology...”⁴⁰

The effect of product liability in promoting product safety relates not only to consumer protection, but to competitiveness. As Professor Mark Hager of American University testified:

. . . our products, because of their superior reputation for safety, due in part to the effects of product liability over the last 20 years, have a superior reputation in the international marketplace. . . . [W]e cannot compete at this time with the low labor costs of newly industrializing countries, but we can compete very effectively . . . in safety, and it would be a grave risk to our international competitiveness to toy with the tort system that helps bring about that competitive advantage.⁴¹

VI. THE CURRENT SYSTEM PROMOTES IMPORTANT PRINCIPLES OF FEDERALISM

The value of the principles of federalism embodied in our current system of tort law should not be overlooked. As Congressman Mike Box, of the Alabama House of Representatives, has testified:

[t]he issues of proper compensation for injured persons and suitable protections for businesses are matters of social values and public policy that should be addressed at the state level, in the absence of a national economic crisis. . . . Arguments for uniform laws as a means of promoting competitiveness ignore the advantages of a decentralized and federal system of civil justice. . . . Remember why we developed as a federal nation. . . . Our founding fathers recognized the importance of having governments responsive to the electorate. Broad powers were reserved to the states so they would serve as bulwarks of freedom, an antidote to an overpowerful national government. . . . S. 1400 [a similar bill introduced the 101st Congress] is radical because it opens the door to substantially greater federal intrusions.⁴²

These concerns were reiterated during the Consumer Subcommittee’s September 12, 1991 hearing by Delegate Bernard Cohen on behalf of the National Conference of State Legislatures. Delegate Cohen pointed out that federal “preemption should not occur unless it could be proved that the variation in State laws is significantly impeding commerce among the States and unless the specific legislative response is the only way to resolve the conflict. . . . [T]his burden has not been met with respect to product liability laws.” Delegate Cohen went on to note that, not only had the burden of

⁴⁰ Letter from Professor Nicholas Ashford to Senator Ernest Hollings, October 1, 1991, submitted for the record of the Consumer Subcommittee hearing on S. 640, September 19, 1991.

⁴¹ Testimony of Professor Mark Hager, Assistant Professor of Law, Washington College of Law, American University, at Consumer Subcommittee Hearing on S. 1400, April 5, 1990, transcript at 126.

⁴² Testimony of Rep. Mike Box, Alabama House of Representatives, at Consumer Subcommittee Hearing on S. 1400, April 5, 1990, Statement at 1-3.

proof not been met, but “the basic rationale for this bill, the underlying rationale for it, is fallacious.”⁴³

Professor Eisenberg from Cornell Law School also has raised these concerns, and pointed out the practical problem with federal tort law that I believe should provoke serious concern:

The changing nature of products liability law makes me cautious about wishing for Congress to implement a single rule. For the rule Congress adopts had better be a good one, since it may preempt further experimentation and change by the states. I see no basis for believing that the rules embodied in S. 1400 [a similar bill introduced in the 101st Congress] are superior to the collection of rules embodied in various state laws and to the ability of the states to adopt the best rules of their sister states, as those rules evolve over time. The one thing we do know is that state product law does change. I worry that Congress may freeze the law with the wrong set of rules at a time when there is no clear reason to [do so].⁴⁴

Testifying on behalf of the National Conference of State Legislatures at the Committee’s April 4, 1995 hearing, Representative Jeffrey Teitz of the State of Rhode Island stated:

This is a unique moment in our national history. For the first time in decades, we have begun a serious re-examination of the relationship between Washington and the fifty state capitals. Members of Congress on both sides of the aisle are publicly acknowledging that the federal government needs to return significant governmental authority on a broad range of issues to the states. There is a widely-shared recognition that dictates from Washington have in many instances made government neither more efficient nor more equitable. Against this great historic trend comes the dubious idea of product liability preemption. The proponents of this legislation want Washington to dictate the legal standards and evidentiary rules which the fifty state court systems use to adjudicate disputes over allegedly defective products. There is no precedent for such a congressional imposition of federal rules by which state courts will be forced to decide civil disputes. . . . The issues of proper compensation for injured persons and suitable protections for businesses are matters of social values and public policy that should be addressed at the state level. Only with clear proof of the need and the effectiveness of national rather than state solutions should we consider the sweeping preemption of state laws and constitutions con-

⁴³Testimony of Delegate Bernard Cohen, Virginia House of Delegates, Consumer Subcommittee Hearing on S. 640, September 12, 1991, transcript at 85-86; 87.

⁴⁴Testimony of Professor Theodore Eisenberg, Professor of Law, Cornell University, in response to post hearing questions of Senator Rockefeller, from Consumer Subcommittee Hearing on S. 1400, April 5, 1990, at 2.

templated by this legislation. In our view, proof of need and effectiveness is lacking.⁴⁵

Indeed, I have this same concern. I am constantly surprised that some are willing to take their chances with Congress setting the rules over the long haul. Such an effort would limit flexibility, and could eventually result in rules more oriented toward plaintiffs than those the states would craft. In any event, we only should tinker with the fundamental principles of federalism in the most extreme circumstances. A record such as we have on this issue is insufficient to take such action.

VII. THE CURRENT SYSTEM DID NOT CAUSE THE INSURANCE "CRISIS"

In past years, the cry for product liability law has been based on a "crisis" in the availability and price of insurance. That argument has become non-existent, since virtually everyone agrees that insurance is now generally available and well-priced—we are in a "soft" market. Even before that occurred, however, it was clear that the product liability system did not cause and was not responsible for insurance availability problems.

The primary allegations concerning the existence and magnitude of this crisis have proved vastly exaggerated. In 1976, the Federal Government created a Federal Interagency Task Force on Product Liability (hereinafter the Task Force) to examine the problem. The Insurance Study commissioned by the Task Force found that, while insurance costs did increase in the mid-1970s, insurance premiums exceeded 1 percent of the total sales for only three industries.⁴⁶ In an April 25, 1980 letter to Senator Adlai Stevenson, Victor Schwartz, in his capacity as Chairman of the Commerce Department's Task Force on Product Liability and now one of the leading advocates of S. 648, stated that "no one has ever demonstrated that the huge increases in product liability premiums in recent years were related to the number and/or size of product liability claims."⁴⁷

By 1983, evidence indicated that product liability insurance costs actually had stabilized or decreased, and that the insurance crisis had disappeared. A 1983 Institute for Civil Justice study concluded not only that reports of a product liability crisis in the mid-1970s were greatly exaggerated, but that even the perception of a crisis had receded because it had become evident that product liability claims had not imposed unreasonable costs on most manufacturers.⁴⁸ Costs increased and availability decreased again in the mid-1980s.

Professors Henderson and Eisenberg noted, in their 1992 study on civil filings, that their data showed little linkage between tort reform and declining insurance rates, and that one has to be skep-

⁴⁵ See Testimony of Jeffrey Teitz, Consumer Affairs, foreign Commerce and Tourism Subcommittee Hearing on S. 565 (April 4, 1995).

⁴⁶ U.S. Department of Commerce, Interagency Task Force on Product Liability, Final Report VI-20 (1977) [hereinafter cited as Task Force Final Report].

⁴⁷ Testimony of Victor Schwartz, Commerce Committee Hearing on S. 1789, 96th Congress (April 22, 1980). Rand Corporation, The Institute for Civil Justice, "Designing Safer Products: Corporate Responses to Product Liability Law and Regulation 121" (1983) [hereinafter cited as Designing Safer Products].

⁴⁸ Rand Corporation, The Institute for Civil Justice, "Designing Safer Products: Corporate Responses to Product Liability Law and Regulation 121" (1983) [hereinafter cited as Designing Safer Products].

tical of such linkage.⁴⁹ According to Professors Henderson and Eisenberg, at the advent of the so-called tort reform movement, reformers were concerned more about convincing the American public that there was a crisis and linking the alleged crisis to product liability, than about the reality of the crisis itself.⁵⁰ The idea was to tie the product liability system to the crisis in a way that reshaped public opinion.⁵¹ Efforts were forcefully made to link the so-called crisis to basic American activities, such as Little League baseball and the Boy Scouts⁵²—almost literally motherhood and apple pie. To quote Professors Henderson and Eisenberg, “using every technique of modern media-shaping, tort reform groups sought to insure that the public believed that products liability law was the cause of this threat to their way of life.”⁵³

During the mid-1980s, the Director of Government Affairs for the Risk and Insurance Management Society—an association of corporate risk managers which generally supports tort reform—himself expressed concern about linking tort reform and the insurance availability crisis.⁵⁴

There is ample evidence that the increases in product liability insurance costs that did occur were actually the result of the cyclical nature of the insurance industry and insurance companies’ underwriting practices, not the product liability system. The Congressional Research Service (CRS) has described the repeating cycles of high and low premiums as a historical alteration between soft and hard insurance markets, and has discussed the management practices of the companies which contribute to this cycle. In a soft market, rates are adequate, and risk selection careful, and the industry generally performs well. New capital is attracted from a number of sources and capacity increases. Price cutting of premiums results when new sources of capacity begin to generate increased competition for available premium volume. Underwriting standards (the standards for deciding whether to insure a particular manufacturer) for risk selection diminish with increased competition, and insurers take on riskier business endeavors. According to CRS, this practice results in rising claims losses.

At the point that competition is severe and losses are too high, insurers withdraw from the market and the capacity shrinks, resulting in a hard market. Availability and affordability problems ensue as the remaining insurers raise prices and tighten the underwriting standards. Eventually the market stabilizes, a soft market emerges, and the cycle begins again.⁵⁵

Interest rates, which reached historic heights in the late 1970s, aggravated the cycle. Companies engaged in price wars in order to obtain a larger volume of premium income for investment.⁵⁶ Basically, companies were willing to accept lower premiums for certain

⁴⁹ Supra at 8, 792.

⁵⁰ Id. at 792-793.

⁵¹ Id.

⁵² Id.

⁵³ Id.

⁵⁴ Id.

⁵⁵ See Congressional Research Service, “Property-Casualty Insurance Market Operation”, CRS Report No. 85-629E (March 20, 1985).

⁵⁶ See “A Rate War Rips Casualty Insurers,” *Business Week*, December 8, 1980.

insurance lines in order to encourage sales and obtain funds for investments.⁵⁷

On February 19 and March 4, 1986, the Committee held hearings to conduct a more comprehensive examination of the availability and cost of liability insurance. Testimony was presented at hearings on the reasons for the insurance crisis. Witnesses noted that the insurance crisis had arisen during a period of falling interest rates, prior to which competing insurance companies had been underpricing their product in order to maximize cash flow and enhance investment income. When interest rates began to fall, companies were forced to increase premiums because investment income was no longer compensating for underwriting losses. The Committee Report accompanying S. 2129, the Risk Retention Amendments of 1986, states that “[t]his practice of cash flow underwriting was linked directly to the current crisis.”⁵⁸

GAO testified in May 1986 before the Consumer Subcommittee that the underwriting cycle turned again and “is now moving in a positive direction.” The property/casualty industry will enjoy “an expected net gain before taxes of more than \$90 billion over the years 1986-1990.”⁵⁹ According to the Insurance Information Institute, the insurance industry has been a very profitable industry over the past decade, even during the 1980s’ insurance crisis. A compilation of the Institute’s annual statistics shows that, between 1984 and 1996, property/casualty companies had a net after-tax income of well over \$100 billion, and an increase in surplus of \$63 billion to \$236 billion.⁶⁰ The strong capacity of the insurance market has been reflected in recent reports on liability premium rates. A report by the National Association of Insurance Commissioners (NAIC) shows that between 1989 and 1993, there was a 26% decrease in product liability insurance premiums.⁶¹

The strength of the insurance market also demonstrates that insurance is available for companies wishing to bring new products to the market.

VIII. PRODUCT LIABILITY IS NOT A MAJOR FACTOR IN THE COMPETITIVENESS OF U.S. BUSINESS

The proponents also claim that product liability is inhibiting the ability of U.S. business to compete in world markets and to market innovative products. However, there is absolutely no evidence that product liability hinders the competitiveness of American businesses.

A recent survey by the Risk and Insurance Management Society (RIMS), an organization comprised of the largest industrial corporations, revealed that liability insurance costs for most busi-

⁵⁷Hearing on Product Liability before the Consumer Subcommittee, 99th Cong. 2d. Sess. (1986) (hereafter cited as 1986 Product Liability Hearing). (Statement of Johnny C. Finch, Senior Associate Director, General Government Division General Account Office) (Testimony on file at Senate Committee on Commerce, Science, and Transportation).

⁵⁸S. Rep. No. 294, 99th Cong., 2nd Sess. 4 (1986).

⁵⁹1986 Hearing on Product Liability, *supra* note 25 (Statement of Johnny C. Finch, Senior Associate Director, General Government Division General Account Office) (Testimony on file at Senate Committee on Commerce, Science and Transportation). U.S. Congress, Office of Technology Assessment, “Making Things Better: Competing in Manufacturing,” OTA-ITE-443 (Washington, D.C.: U.S. Government Printing Office, February 1990).

⁶⁰Insurance Information Institute Annual Statistics on Property/Casualty Companies.

⁶¹NAIC Research Quarterly, Volume 1, Issue 1 (January 1995 at 23).

nesses are less than 1% of total revenues. The RIMS study is similar to earlier finding the Conference Board.⁶²

In 1987, the Conference Board surveyed risk managers of 232 major U.S. manufacturing, trade, and service corporations about the effect of product liability on their companies.⁶³ Risk managers are the corporate employees that have the greatest corporate responsibility for addressing product liability issues—40 percent, as compared to a 6 percent responsibility by the Chief Executive Officers (CEOs).⁶⁴ Two-thirds of the risk managers said that product liability contributed 1 percent or less to the final prices of their products. For another 11 percent of the companies, the liability cost was only 2-3 percent of the final price.⁶⁵ Additionally, most of the companies surveyed said that the area in which product liability had most significantly altered management decision making was in the quality of the products themselves.⁶⁶

The GAO made similar findings in a 1988 report on the issue. GAO found that insurance costs represented a relatively small proportion of businesses' annual gross receipts—0.6 percent for large businesses, and about 1 percent for small businesses.⁶⁷

Additionally, the Institute for Civil Justice of the Rand Corporation concluded in 1983 that product liability costs in most cases were only a minute percentage of costs to business:

It appears safe to conclude that for most large manufacturing firms, product liability costs—including the cost of defending litigation and certain product liability prevention activities—probably amount to much less than 1 percent of total sales revenue.⁶⁸

Also, the Rand Corporation has found that only a small percentage of U.S. manufacturers are even involved in product liability litigation. In 1986, only 0.9 percent of all manufacturing concerns in the United States were defendants in product liability litigation.⁶⁹

A recent study by Robert Hunter, former Texas Insurance Commissioner, and currently Director of the Insurance Division of the Consumer Federation of America, found that product liability accounts for only 26 cents of each \$100 of retail sales in the country.⁷⁰

In its study of competitiveness, the Office of Technology Assessment (OTA) concluded that American manufacturing clearly is being challenged by competitors, particularly from Japan. However, the recommended policy options for government activity to address this challenge did not include federal product liability law. Rather, OTA listed the four most important steps that the United States

⁶²Risk and Insurance Management Society (RIMS) 1994 Cost of Risk Survey (See Executive Summary)

⁶³Weber, "Product Liability: The Corporate Response," The Conference Board, Report No. 893 (1987).

⁶⁴*Id.* at v.

⁶⁵*Id.* at 13.

⁶⁶*Id.* at 2.

⁶⁷U.S. General Accounting Office, "Liability Insurance: Effects of Recent 'Crisis' on Businesses and Other Organizations," GAO/HRD-88-64 (July 1988).

⁶⁸Designing Safer Products, *supra*, note 22 at 121.

⁶⁹Dugworth, "Product Liability and the Business Sector: Litigation Trends in Federal Courts," Rand Corporation, the Institute for Civil Justice, R-3668-ICJ (1988).

⁷⁰See testimony of Robert Hunter, Consumer Affairs, Foreign Commerce and Tourism Subcommittee Hearing on S. 565 (April 3, 1995).

could take to improve competitiveness: (1) lower the cost of capital; (2) improve the quality of human resources through education and quality of workforce; (3) improve the diffusion of manufacturing technology to small and medium-sized business; and (4) provide government funding of risky but promising long-term research and development.⁷¹

Claims regarding the cost of the liability system to businesses have been based on unsupported claims. Such rhetoric was greatly espoused by the Council on Competitiveness, under the auspices of former Vice President Quayle. The Council claimed that the cost of the tort system was crippling U.S. business, using questionable factors to derive the total cost of the system. Upon scrutiny, these dollar amounts were completely without factual basis.

Mr. Quayle asserted that the "direct" costs of the tort system are \$80 billion per year, and that indirect costs were considerably higher. The "authority" cited for that figure was *Forbes* magazine, which in turn cited no authority. The figure can be located in only one other place I have been able to uncover—Peter Huber's book, "Liability: The Legal Revolution and Its Consequences." However, as an analysis of this book for the *Stanford Law Review* points out, this number was simply lifted from a comment made by Robert Malott, Chairman of the Business Roundtable's product liability task force and CEO of the FMC Corporation, in the 1986 issue of *Chief Executive* magazine. Mr. Malott was quoted as saying, "insurance liability costs industry about \$80 billion per year" with no documentation for that remark.⁷² These "authorities" speak for themselves about the extent to which we should rely on these estimates in deciding to overhaul the civil justice system.

The only other discordant note in the general agreement that product liability has a very small impact on business comes from a 1988 Conference Board survey of 500 chief executive officers of corporations, 42 percent of whom stated that product liability had a major impact on them.⁷³ Some components of the Conference Board apparently were dissatisfied with the results of their 1987 survey, cited above, which did not support their theory of product liability. So they decided to ask different people, in hopes of a different result. This is virtually the only piece of information cited by the supporters of this legislation for the proposition that product liability affects competitiveness.⁷⁴

However, as Professor Theodore Eisenberg of Cornell Law School has stated with respect to this survey, "* * * the case for reducing defendant liability seemed rather weak. It depended in large part on a survey of CEOs in which they were asked whether products liability was a problem for their companies. The flaws in such a survey are so substantial and obvious that no self-respecting legislature should act on the basis of the results."⁷⁵ I could not have said it better myself. We cannot responsibly move forward on this

⁷¹ Testimony of Dr. Julie Fox Gorte, Office of Technology Assessment, Consumer Subcommittee Hearing on S. 1400, April 5, 1990 at transcript pp. 61-2.

⁷² Hager, "Civil Compensation and Its Discontents: A Response to Huber," 42 *Stanford L. Rev.* 539, 547-550 (January 1990).

⁷³ McGuire, "The Impact of Product Liability," The Conference Board, Report No. 908 (1988).

⁷⁴ See, e.g., Testimony of Wendell Wilkie, General Counsel, Department of Commerce, Consumer Subcommittee Hearing on S. 1400, February 22, 1990.

⁷⁵ Responses of Professor Theodore Eisenberg, Professor of Law, Cornell University, to post-hearing questions of Senator Rockefeller, April 10, 1990, response to question 1.

legislation based on a self-serving survey of corporate executives, particularly when it is contrary to all other data. The data demonstrate that the actual impact of product liability on businesses' bottom line is very small.

What is truly troubling about this debate over competitiveness is not the effect of the tort system on business, but the total lack of reliable information on which this competitiveness claim is based. In 1991, the GAO released a study of the effects of product liability on competitiveness, and stated that it could find no acceptable methodology for relating product liability to competitiveness, and that businesses refuse to make available the information necessary to conduct such analysis.⁷⁶

It has been argued that product liability costs are much higher in the United States than in the countries of some of our foreign competitors. However, a direct comparison of the costs of the tort systems in various countries, without more, is not valid because it ignores other types of compensation systems available in other countries. For example, in the Netherlands several social insurance programs are available which may preempt the need for compensation through the litigation process—the ZW/Sick Statute; the ZFW/Sick Fund Law; the WAO/Workers Disability Act of 1967; the AAW/General Act on Disability of Work; and the AWBZ/General Act on Special Medical Costs. The ZW is funded by collecting 5 percent of employers' gross income and 1 percent of employees' gross income. An injured employee may receive up to 70 percent of earned wages for 1 year. AAW and WAO continue funding if further assistance is needed.⁷⁷

Moreover, the tax burden on business in the various countries must be included in any calculus of the relative competitive status of business. Taxes on business are higher in virtually every advanced country than they are in the United States.⁷⁸

Thus, while business' costs related directly to the tort system may be lower in other countries, the relevant comparison is between the overall cost of compensation, which is likely to be similar to that in the United States. The proof of the fact that U.S. laws do not unduly burden companies doing business here is that foreign businesses are increasingly trying to locate here. In fact, foreign businesses would not seek to locate here if the tort system were the crippling burden that has been suggested by the proponents of S. 648.

It is clear that the facts do not support this contention that the current product liability system puts American businesses at a competitive disadvantage. Very recently, the National Association of Manufacturers issued a report boasting about the global competitiveness of U.S. manufacturers.⁷⁹ The report showed that U.S. exports increased from over \$150 billion in 1986 to over \$300 billion in 1991. If we are going to legislate to assist American business,

⁷⁶ GAO, "Product Liability rates and Claims, HRD 91-108 (1991).

⁷⁷ Mann and Rodrigues, "The European Directive on Products Liability: The Promise of Progress?" 18 Ga. J. Int'l & Comp. L. 391, 416.

⁷⁸ Testimony of John G. Wilkins, Director of Tax Policy for Economic Analysis, Coopers and Lybrand, before the House Committee on Ways and Means, hearing on factors affecting U.S. international competitiveness, July 18, 1991.

⁷⁹ "The Facts about Modern Manufacturing," the Manufacturing Institute (July 1992 at 3).

we should do it in a way that will be effective, and S. 648 will not be.

IX. S. 648 WILL NOT REDUCE PRODUCT LIABILITY COSTS FOR BUSINESS

Even if we assume that product liability is a significant barrier to the ability of U.S. firms to compete in world markets, that barrier cannot be reduced by any legislation unless the legislation somehow reduces businesses' costs. As J. Robert Hunter, then President of the National Insurance Consumer Organization, testified, "[m]ake no mistake about it, if insurance costs and availability are not improved, competitiveness is not affected."⁸⁰

The Committee, in hearings over the last several years, has received virtually unequivocal testimony that enactment of bills such as S. 648 will not affect costs or insurance rates. The insurance industry testified before the Committee regarding a bill similar to S. 648 in no uncertain terms that ". . . the bill is likely to have little or no beneficial impact on the frequency and severity of product liability claims. . . . [I]t is not likely to reduce insurance claim costs or improve the insurance market."⁸¹

Indeed, that the bill will not have its purported effects becomes clear when its actual impact is reviewed. For example, it is claimed that the bill will provide additional uniformity in product liability law nationwide. However, the bill only selectively preempts state law, leaving much of state law in place to be interpreted with the new federal law. Additionally, it provides a federal rule of law to be interpreted by both the state and the federal courts, but it is questionable whether state courts can be bound by the decisions of federal courts other than the Supreme Court.

As Professor Eisenberg testified,

. . . for a period of time, at least, predictability may be reduced rather than increased. Each state will have to decide the scope of S. 1400's [a similar bill introduced in the 101st Congress] preemption and its relation to state tort law. The interaction between state and federal law in tort will be made more rather than less complex. . . . [U]niformity will not be quickly, if ever, achieved. . . . [We] are at risk of having not just 55 jurisdictions but an additional dozen federal courts of appeals making products law. At least before enactment of S. 1400 the [federal] courts of appeals should have felt bound by state law. Until the Supreme Court speaks, it is not clear that state supreme courts would or should be bound by federal interpretations of S. 1400 as it interacts with the relevant state law.⁸²

⁸⁰Testimony of J. Robert Hunter, President, National Insurance Consumer Organization, Consumer Subcommittee hearings on S. 1400, April 5, 1990, at 132.

⁸¹Testimony of Deborah T. Ballen, Vice President for Policy Development and Research, American Insurance Association, at Consumer Subcommittee Hearing on S. 1400, April 5, 1990, transcript p. 110.

⁸²Testimony of Professor Theodore Eisenberg, Cornell Law School, Responses to post-hearing questions of Senator Rockefeller at 3. See also Note, "Authority in State Court of Lower Federal Court Decisions on National Law," 48 Columbia L.Rev. 943, 954 (1948); Stern and Grossman, Supreme Court Practice (5th ed. 1978) at 280; *Testa v. Katt*, 330 U.S. 386 (1947).

With respect to punitive damages, S. 648 provides a standard of proof for punitive damages that is more restrictive than that in many states. However, punitive damages are not a significant factor in product liability cases. As Professor Eisenberg has stated, “[t]here is a widespread perception that punitive damages are awarded frequently and in great amounts. Yet every serious study of the area finds that punitive damage awards are relatively infrequent, that they usually are commensurate with the defendant’s wrongdoing, and that they bear a substantial relationship to the size of the compensatory awards. . . . [P]unitive damages are awarded in not more than one percent of filed cases”⁸³ The 1989 GAO Report also looked at punitive damages, and found that, on the few occasions when they were awarded, their amount had a high correlation with the amount of compensatory damages.⁸⁴

In fact, regardless of the scope of the product liability legislation enacted, the record indicates that it will be ineffective in reducing product liability insurance costs. For example, Florida passed very strong changes in its tort law in 1986, and also required the insurance industry to make rate filings indicating the effect of the changes on its rates. The Florida law eliminated joint and several liability, limited non-economic damages to \$450,000, and limited punitive damages. Nevertheless, when Aetna’s rate filing came in, it listed the effect of each change on its rates as “zero.”⁸⁵ There was no change in insurance costs, despite the dramatic changes in tort law, and we could expect none with enactment of S. 648.

No explanation has been offered, and none could logically be offered, for any way in which a bill could improve competitiveness if it does not reduce product liability claims or costs. When this is pointed out, the supporters of the bill often suggest that the bill may not reduce damages paid but will reduce “transaction costs”, or the costs of litigation such as attorneys’ fees. But it is obvious, that if transaction costs were reduced, they should be reflected in reduced insurance costs. However, experts have testified that insurance costs will not be reduced by this bill. The available evidence demonstrates that the bill will not reduce transaction costs, either.

GAO has stated unequivocally:

[w]e believe that S. 1400 [a similar bill introduced in the 101st Congress] is unlikely to reduce transaction costs in product liability suits. For cases that are litigated, the procedural features of the tort system would not be changed by the bill. It is also not clear that the bill provides strong incentives for alternative dispute resolution, which could cut litigation costs. Moreover, the alternative dispute resolution mechanisms that may be used are left to the discretion of the states. If these mechanisms are not binding, then they may add to rather than substitute for litigation. If this happened, costs could actually increase.

⁸³ Testimony of Professor Theodore Eisenberg, Responses to Post-hearing questions of Senator Rockefeller *supra*, at 4-6 and authorities cited therein.

⁸⁴ 1989 GAO Report, *supra*, at 27.

⁸⁵ Testimony of J. Robert Hunter, *supra*, transcript at 135.

GAO went on to note that transaction costs are largely a function of the length of litigation, and that delays caused by defendants are common. However, if a complete and accurate record is necessary to insure a fair outcome of the case, “lengthy litigation and its attendant costs might be justified.”⁸⁶

Another justification offered for federal product liability legislation is that legal fees paid to plaintiffs’ attorneys are too high. However, this bill would not have any effect on attorneys’ fees. In any event, it is important to understand the value of the current system of compensation for plaintiffs’ attorneys. Plaintiffs’ lawyers who accept product liability cases work on a contingency fee basis. If they win the case they get a percentage of the case (which is usually about 30 percent); if they lose, they get nothing. This system allows injured plaintiffs who are not wealthy to obtain a lawyer. At the same time, the system acts as a deterrent to frivolous cases because attorneys are spending their own time and money in the case.

Figures from the Institute for Civil Justice state that plaintiffs receive approximately one-half of the cost of litigation. Any problem with the cost of the system is not with the cost of the attorney who is “investing” his or her own time and money to win a case. The problem is with the defense attorney who has an incentive to delay the case with dilatory motions, and thereby encourage severely injured plaintiffs to settle for less in order to get an expedited payment of the plaintiff’s medical and other costs. Meanwhile, the company is making interest on money that would otherwise be in the hands of the prevailing plaintiff.

The evidence also shows that defendants’ attorneys are apparently better paid, on average, than plaintiffs’ attorneys. According to a recent report by the Consumer Federation of America, for every \$1 paid to plaintiff’s attorneys, at least \$1.31 is paid to defense attorneys.⁸⁷ Of course, defendants’ attorneys are paid regardless of the outcome of the case, while plaintiffs’ attorneys are paid only if they win their cases. Otherwise, they suffer a loss for the time and expenses they have incurred. Thus, existing transaction costs are not inappropriate, and in any event would not be reduced by this bill.

X. THE PRODUCT LIABILITY SYSTEM DOES NOT STIFLE INNOVATION, BUT CAN ENCOURAGE INNOVATIONS IN SAFETY

Another popular argument made in support of the bill is that the current system deters innovation, and discourages new products from being brought to market. Of course, this effect is, by its nature, somewhat subjective and very difficult to examine. However, witnesses at the Committee’s hearings that examined the effects of the tort system on the chemical industry noted that desirable innovation must mean safe innovation, and that if the tort system discourages unsafe innovation, that is valuable. They also found that, even in the chemical industry, in which manufacturers pay a min-

⁸⁶ Testimony of Joseph F. Delfico, Director, Income Security Issues, General Accounting Office, Consumer Subcommittee Hearing on S. 1400, February 22, 1990 in response to post-hearing questions of Senator Bryan at 2.

⁸⁷ Testimony of Robert Hunter, Consumer Affairs, foreign Commerce and Tourism Subcommittee Hearing on S.565 (April 3, 1995)

uscule percentage of the costs of the injuries caused by their products, the tort system works to encourage the innovation of safer products.⁸⁸

Proponents have placed a special emphasis on the impact the system is having on the drug and medical device industries. They claim the drug industry is burdened by the product liability system, and that many life-saving drugs and medical devices are being kept from the market because of litigation concerns. These claims, however, are inconsistent with the views of the drug companies themselves, and reports on the market performance of the U.S. pharmaceutical industry. Testifying before the House Judiciary Committee on August 12, 1994, on behalf of the Pharmaceutical Research and Manufacturers of America (PHRMA), Gerald J. Mossinghoff, PHRMA President at that time, stated:

the U.S. industry is the world leader in developing new medicines. We are responsible for about one-half of all new patented drugs that reached the global market since 1970. Private industry was the source of more than 92% of the new chemical entities approved in the U.S. during 1981–1990.

A recent report by Fortune magazine rated the U.S. pharmaceutical industry the number one American industry with respect to competitiveness. These reports, as well as studies on the strength of the insurance market, make clear that the American drug industry is not being hampered by the product liability system.

Business can, and often does, say it is discouraged from bringing innovative products to market, but it does not say what those products were, so the claim cannot be analyzed. However, those actual products that have been cited by witnesses in support of this claim subsequently had legitimate questions raised about their safety. In such cases, until such questions are resolved, I do not think we should presume that the product liability system has not worked properly to keep those products from the market.

Some examples of products cited as unfairly kept from the market by the system are set out below, together with the facts as they developed through the Committee's hearing process.

Monsanto Asbestos Substitute—Calcium sodium metaphosphate was cited by several supporters of S. 640 [a bill considered in the 102nd Congress] as a primary example of a safe product kept from the market by the product liability system. However, an Environmental Protection Agency (EPA) Status Report dated August 19, 1986, reviewed studies of this product submitted by Monsanto, and stated that "EPA believes that the evidence obtained from Monsanto's . . . study in rats offers reasonable support for the conclusion that calcium sodium metaphosphate fibers can cause cancer." (Report p. 9). Dr. Philip Landrigan, Chairman, Department of Community Medicine, Mt. Sinai Medical Center, reviewed the EPA and Monsanto documents, and stated: "I am extremely concerned about the potential carcinogenicity of sodium calcium

⁸⁸ Ashford and Stone, *supra.*, at 415, 417.

metaphosphate.”⁸⁹ Monsanto’s CEO, Richard Mahoney, subsequently wrote to the Committee stating that later tests of the fiber showed no evidence of health problems, that the first test was not done to determine the health risk to humans, and that the product was kept off the market solely because of concerns about “unwarranted litigation”.⁹⁰ However, this letter does not explain why the first test would have been done if not to examine risks to human health.

Copper 7 IUD—Supporters of S. 687 [a bill considered in the 103rd Congress] claimed that this product, although safe, was taken off the market because of unwarranted product liability suits. The Court in *Kociemba v. Searle*, 707 F. Supp. 1517 (D. Minn. 1989), (settled w/out appeal), a Copper 7 case, stated that the plaintiff “presented evidence which would have allowed a reasonable jury to conclude that defendant knowingly placed millions of American women, especially [women who have not had children], at risk of serious infection, loss of fertility, and surgery for removal of internal organs” and that “responsibility for this conduct was shared throughout defendant’s corporate hierarchy, and that the conduct continued for over ten years.” Michael Ciresi, the lawyer who litigated many Copper 7 cases for plaintiffs, has written to the Committee stating that his firm spent millions of dollars on discovery of documents that Searle resisted through litigation to the Supreme Court. Cases litigated before completion of that discovery were not successful because of the lack of documentation. According to Mr. Ciresi, the documents ultimately obtained demonstrated that the company knew the product was dangerous to women who have never had children, but continued to market the product to those women. That action was the basis for punitive damages against the company.⁹¹

Sturm Ruger “Old Model” Single Action Revolver—This product was cited as one which was the victim of unreasonable verdicts based on injuries that were really due to plaintiff negligence. However, documents submitted at the Committee’s May 10, 1990 hearing demonstrated that since 1962 Ruger had received reports of serious injuries and deaths resulting from accidental discharges of this gun. In 1968, the gun failed a test for accidental discharge performed by the Bureau of Alcohol, Tobacco and Firearms, and it subsequently failed Ruger’s own tests. Ruger did not redesign the gun to add a transfer bar safety device until 1973, and estimated that between 1968 and 1973 more than 150,000 “old models” were sold. Bill Ruger, CEO of the company, testified during product liability litigation that no safety device was put on the gun because a revolver “is supposed to be designed in the traditional way.” The Court in *Sturm Ruger v. Day*, 594 P.2d 38 (Alaska 1979) found Ruger liable for punitive damages for failure to add a safety device. According to testimony before the Committee, by 1989 about 230

⁸⁹ Report of Dr. Phillip Landrigan.

⁹⁰ Letter from Richard Mahoney to Senator Richard H. Bryan dated May 17, 1990, reprinted in record of Consumer Subcommittee Hearing on S. 1400, May 10, 1990.

⁹¹ Statement of Michael Ciresi, submitted for record of Consumer Subcommittee Hearing on S. 1400, April 5, 1990.

product liability claims had been filed against Ruger for this defect, but the gun has never been recalled.⁹²

Puritan-Bennett Anesthesia Gas Machines—This was cited by some hearing witnesses as a product unjustly removed from the market by the product liability system. The machines were implicated in four deaths in 1983–84. Hearings in the House Subcommittee on Oversight and Investigations, September 24, 1984, found that the company failed to notify the Food and Drug Administration (FDA) of deaths that were caused by an overdose of anesthesia due to swelling of “O” rings and resultant sticking of a valve. This problem was known in the 1970s, and reflected in an appendix to the 1979 voluntary standard for anesthesia machines. The FDA, testifying before the subcommittee in 1984, stated that the company “appears . . . [to have] failed to conduct adequate design review of certain critical components” including use of certain rubber-like materials in the presence of high concentrations of anesthetic gas. The company instituted a limited recall, and the FDA required the recall extended to all valves distributed through July 1984.⁹³

Ortho Contraceptives—Witnesses at the Committee’s hearings claimed these products were unfairly subjected to product liability actions, citing *Wooderson V. Ortho*, 681 P.2d 1038, cert. denied 105 S.Ct. 365 (1984). It was claimed that, in that case, the company was held liable for failure to warn even though the FDA had determined that the warning was not necessary. However, an examination of the Court’s decision reveals that the Court held that there was no clear determination by the FDA as to whether such a warning was necessary, so that the defense was not valid. Ortho was held liable by the Court for punitive damages because it ignored substantial evidence that its product caused renal failure.

Taking all the evidence presented on both sides of these issues, I am not prepared to conclude that the current product liability system is not working properly to insure the safety of new products.

S. 648 IS SUBSTANTIVELY FLAWED

As I stated in previous reports, this legislation dramatically revises our current legal system without any serious factual predicate for such a change. The purported intent of S. 648 is to create uniformity through federal preemption of state law. In reality, however, the bill provides for only selective, and in many instances, only one-way preemption. Moreover, the bill, for the most part, only preempts state law to the extent the law favors consumers. Laws that are considered favorable to defendants are preserved by the bill. The legislation also contains many inconsistencies and substantive legal problems. A few examples are set out below.

1. SECTION 108—PUNITIVE DAMAGES

Section 108 of the bill is cited as “Uniform Standards For Award of Punitive Damages.” By including such standards, the bill’s sup-

⁹²Supplemental Statement of Linda Lipsen, submitted for record of Consumer Subcommittee Hearing on S. 1400, May 10, 1990.

⁹³Supplemental statement of Linda Lipsen, *supra*, reprinted in record of Consumer Subcommittee Hearing on S. 1400, May 10, 1990.

porters are acknowledging that such damages are important in deterring outrageous and unacceptable behavior by manufacturers. However, by its terms, it applies to punitive damages only “if otherwise permitted by applicable law” Thus, in states which have, through state law, eliminated or limited punitive damages, this bill would not restore the availability of such damages. In some states, there would be no right to punitive damages; in other states they would be capped at a stated amount; and they would be available only if the burden of proof in this legislation is met. This clearly does not, and is not intended to, create uniformity in the law of punitive damages. If proponents truly wanted uniformity, and were serious about deterring egregious conduct, they, at a minimum, would restore punitive damages in the states that have limited them so that the law would be consistent nationwide. As Professor Lucinda Finley of the Buffalo School of Law stated in testimony before the Committee on April 4, 1995, “to advance the goal of uniformity, punitive damages ought to be equally available to injured people without regard to what state they reside in.”⁹⁴

A. PROVISION DISCRIMINATES IN FAVOR OF WEALTHY CITIZENS

Section 108 caps punitive damages at \$250,000 or two times the claimant’s economic and non-economic (pain and suffering) damages, whichever is greater. Because of the connection to economic losses, juries and courts will be permitted to grant higher punitive awards in cases involving wealthy citizens. The obvious message of this provision is that companies should be punished more for injuring wealthy persons.

This standard will have the effect of permitting persons with higher economic losses (e.g., wages, business opportunities), to collect more in punitive damages than persons with lower economic losses. The implied message, of course, is that injuries to persons with higher incomes and salaries (i.e., wealthy citizens) should be punished more than harm caused to lower-wage earners (i.e., working-class citizens or women who are homemakers).

B. THE JUDGE USURPS THE JURY’S POWER

A provision has been included to allow a judge to increase punitive damages, if the cap was determined to be inadequate. The provision would supposedly alleviate the effects of disparate treatment based on economic status. However, the Supreme Court has ruled that juries, not judges, are to retain the ultimate authority to determine damages.⁹⁵

It should be noted that the legislation does not permit the court to inform juries about the caps on punitives. Thus, when a jury deliberates on punitive damages, it is unaware that there is a cap. If the jury happens to render a punitive verdict that exceeds the cap, the judge is required to negate the amount in excess of the cap.

At that point, the judge is permitted to hold a separate proceeding—independently of the jury—to consider increasing the punitive

⁹⁴ See Testimony of Lucinda Finley, Consumer Affairs, Foreign Commerce and Tourism Subcommittee Hearing on S. 565 (April 4, 1995).

⁹⁵ *Dimick v. Schiedt*, 293 U.S. 474 (1935).

award beyond the cap. The judge can award any increase, as long as it does not exceed the amount initially granted by the jury. This does not make the legislation constitutional, however. At this stage in the process, the jury's verdict is merely used as a gauge, or measure, for the judge, acting independently of the jury. The reality is that the judge is given authority to increase punitive damages beyond the cap—authority that is not given to the jury. Unlike the judge, the jury can never, acting on its own, render a punitive verdict that exceeds the cap. Any amount of the jury's award that supersedes the cap is to be vitiated immediately by the judge.

This mechanism is unconstitutional since it grants judges greater powers to determine damages than juries. Although in some instances a judge may reduce a jury's award, a judge is not to be given authority to determine damages that supersede the authority of the jury.

This provision assuredly will be challenged by business lawyers as unconstitutional. The end result will be that the provision will be removed and the cap—in its discriminatory form—will remain.

C. PUNITIVE DAMAGES PROVISION IS BAD POLICY

The proponents claim they have attempted to rectify the unfairness of the punitive damage provision by allowing judges to increase damages beyond the cap. However, such efforts have amounted to no more than a failed attempt to correct bad policy. The simple fact is that Congress should not pass a bill it admits is unfair, and then delegate responsibility to judges to correct the unfairness. Additionally, a judge is not permitted to determine damages based on whether the law is fair to working and lower income citizens. Such reasoning, on its face, is wholly unconstitutional.

2. SECTION 106—STATUTE OF REPOSE

Section 106 includes an 18-year statute of repose provision. The provision bars the right of an injured person to recover for damages for injuries caused by a product 18 years old or older. This provision in S. 648 includes a two-way preemptive provision. Proponents claim the inclusion of the two-way preemptive provision has made the bill more beneficial to consumers.

A. PROVISION EXPANDED TO COVER ALL CONSUMER PRODUCTS

What the bill's supporters failed to point out, however, is that the statute of repose proposals in previous bills were limited to workplace products. In S. 648, however, the provision has been expanded to apply to all consumer products. These products include: elevators, playground equipment, construction equipment, amusement parks, ski lifts, cargo airplanes, furnaces, hot water heaters, garage doors, and power tools.

B. ABOLISHES RIGHTS CONSUMERS CURRENTLY HAVE IN OVER 30 STATES

According to CRS, the bill would restrict the rights of citizens in over 30 states that do not have any limitations on their right to sue when injured by defective products.

Of the approximately 17 states that have a statute of repose, 15 include various exceptions for certain products, such as contraceptives or products that may have hidden defects. The bill would eliminate those exceptions.

C. SHIELDS COMPANIES FROM LIABILITY—EVEN IF THE PRODUCT WAS CONSCIOUSLY MANUFACTURED OR SOLD DEFECTIVELY

The legislation provides no exception from the 18-year statute of repose. The bill would shield sellers, lessors, and manufacturers from suit—even if the company knew the product was dangerous, intentionally manufactured the product defectively, or sold the product in the knowledge that it was defective.

Additionally, the provision will have the effect of shielding from liability a significant number of products in use. Howard Fark, a member of the Board of Directors of the National Machine Tool Builders Association, testified at a hearing on S. 1400 [legislation considered in the 101st Congress] that over 50 percent of the claims filed against machine tool builders involve machines at least 25 years old. It is argued that, if machines are defective, the defects will show up before the expiration of an 18-year period, so that manufacturers typically should not be liable for such products after that time. I have no reason to dispute that. However, by the same token, there has been no demonstration that there could never be a defective 21-year-old product, or 26-year-old product for that matter. As long as that possibility exists, it is appropriate to leave the responsibility to decide who should be liable for harm from a product where it now exists in most states—with the jury and the court.

3. SECTION 110—ELIMINATION OF JOINT LIABILITY FOR NON-ECONOMIC DAMAGES

Section 110 states that “the liability of each defendant for non-economic damages shall be several only and shall not be joint.” However, it does not restore the availability of full non-economic damages in states in which such damages have been capped at a certain amount. It does not restore joint and several liability for economic damages in states where such liability has been limited by state law. So, again, we will not have uniform nationwide law on joint and several liability. We will have some states that have no joint and several liability, some that have joint and several liability only in certain circumstances, and some that follow the rule of S. 648.

Data supplied by the Insurance Services Office (ISO) also shows that claims by the bill’s supporters that businesses are paying more than their share of damages are unfounded. According to a recent ISO study, 77% of insured persons involved in multiple-party claims paid a percentage of the total pay-out equal to their relative fault.⁹⁶

⁹⁶ See Insurance Services Office (ISO) Issues Series, “Closed Claim Survey for Commercial General Liability: Survey Results, 1991.”

CONCLUSION

I regret that the Committee has once again proceeded to report legislation to federalize product liability tort law without any comprehensive data to demonstrate (1) that the legislation is necessary, and (2) that the legislation will work. The evidence is clear that this legislation will not have its purported effect of making the civil justice system more efficient or enhancing the competitiveness of American businesses. Our nation's civil justice system is one of the most admired systems of justice in the world. It should be cherished and preserved, not tinkered with, or modified in the interest of singularly self-interested groups.

I believe that, before the Congress delves into this area, it should seek the guidance of the majority of state legislatures and judges, who have handled such matters for over 200 years, as well as legal experts. I did so, and they gave a resounding "no" to this legislation. We would do well to listen to them.

CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, the Committee states that the bill as reported would make no change to existing law.

